



# **National Health (Pharmaceutical Benefits) Regulations 1960**

**Statutory Rules No. 17, 1960**

## **Compilation No. 39**

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Prepared by the Office of Parliamentary Counsel, Canberra

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## About this compilation

### **This compilation**

This is a compilation of the *National Health (Pharmaceutical Benefits) Regulations 1960* that shows the text of the law as amended and in force on 1 April 2015 (the *compilation date*).

This compilation was prepared on 1 April 2015.

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

### **Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on ComLaw ([www.comlaw.gov.au](http://www.comlaw.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on ComLaw for the compiled law.

### **Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### **Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on ComLaw for the compiled law.

### **Self-repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## **Part 1—Preliminary**

### **Division 1.1—Interpretation**

#### **1 Name of Regulations**

These Regulations are the *National Health (Pharmaceutical Benefits) Regulations 1960*.

#### **2 Commencement**

These Regulations shall come into operation on 1 March 1960.

#### **5 Interpretation**

(1) In these Regulations, unless the contrary intention appears:

***applicable amount*** has the same meaning as in Part VII of the Act.

***approved electronic communication*** means an electronic communication of a kind approved in writing by the Secretary under regulation 5E for the purposes of the provision in which the expression is used.

***approved hospital*** means a hospital in respect of which the hospital authority is approved under section 94 of the Act.

***approved hospital authority*** has the meaning given by subsection 84(1) of the Act.

***approved information technology requirements*** means information technology requirements of a kind approved in writing by the Secretary under regulation 5F for the purposes of the provision in which the expression is used.

***approved medical practitioner*** means a medical practitioner approved under section 92 of the Act.

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***approved pharmacist*** has the meaning given by subsection 84(1) of the Act.

Note: The definition in subsection 84(1) of the Act provides that ***approved pharmacist*** means a person for the time being approved under section 90 of the Act and includes certain other persons described in that definition. Under paragraph 91(7)(a) of the Act, a person granted permission to supply pharmaceutical benefits under subsection 91(1) of the Act is to be treated as if the person is approved under section 90 of the Act as an approved pharmacist. Under paragraph 91(7)(c) of the Act, references in the Act to an approval granted under section 90 of the Act include references to an approval treated as having been granted under section 90 by paragraph 91(7)(a) of the Act.

***approved supplier*** has the same meaning as in Part VII of the Act.

***authorised midwife*** has the meaning given by subsection 84(1) of the Act.

***authorised nurse practitioner*** has the meaning given by subsection 84(1) of the Act.

***authorised optometrist*** has the meaning given by subsection 84(1) of the Act.

***authority prescription*** means a prescription that prescribes a pharmaceutical benefit and that has been authorised:

- (a) in accordance with subregulation 13(5); or
- (b) in accordance with authority required procedures that:
  - (i) are part of the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit; or
  - (ii) are part of the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit; or
  - (iii) are incorporated by reference into the circumstances determined for the pharmaceutical benefit under subsection 85B(4) of the Act.

**brand**, for a pharmaceutical item, means a brand of the pharmaceutical item within the meaning of subsection 84(1) of the Act.

**Commonwealth price** has the same meaning as in Part VII of the Act.

**concessional beneficiary** has the same meaning as in Part VII of the Act.

**concession card** has the same meaning as in Part VII of the Act.

**CTS claim** has the meaning given by subsection 84(1) of the Act.

**data collection period**, for a brand of a pharmaceutical item: see regulation 37C.

**deferred supply authorisation** means a deferred supply authorisation prepared under paragraph 26A(2)(a).

**delisted brand**, of a pharmaceutical item: a listed brand of a pharmaceutical item becomes a delisted brand when a determination made under subsection 85(6) of the Act is no longer in force for that brand.

**dependant**, in relation to a concessional beneficiary, has the same meaning as in Part VII of the Act.

**drug in a pharmaceutical item** has the same meaning as in Part VII of the Act.

**electronic communication** has the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

**electronic order form** means a form that is approved in writing by the Secretary under subparagraph 16(1)(b)(ii) for the purposes of lodging an order under paragraph 16(1)(b).

**electronic prescription** means a prescription that is prepared and submitted:

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- (a) in accordance with approved information technology requirements (if any), by means of an approved electronic communication; and
- (b) in accordance with the appropriate form under:
  - (i) sub-subparagraph 19(1)(a)(ia)(B) (prescriptions other than medication chart prescriptions); or
  - (ii) subregulation 19AA(5) (medication chart prescriptions).

**entitlement card** has the same meaning as in Part VII of the Act.

**final day**, in relation to a data collection period, means the last day of the data collection period.

**incentive**, for a brand of a pharmaceutical item, includes anything given as an incentive to take supply of the brand (including a delisted brand before it was delisted) whether the incentive is given:

- (a) before the supply of the brand, but on condition of taking supply; or
- (b) at, or after, the time of the supply of the brand; or
- (c) over a period of time; or
- (d) directly for the brand; or
- (e) indirectly for the brand (for a group of brands of pharmaceutical items or other products, for example).

**information technology requirements** has the meaning given by subsection 5(1) of the *Electronic Transactions Act 1999*.

**initial month**, for a brand of a pharmaceutical item that was not a listed brand immediately before the brand's start day, means the first month of the brand's first data collection period.

**last listed brand**, of a pharmaceutical item, means the brand of the pharmaceutical item that was the last to become a delisted brand before the final day.

**Medicare Australia/DVA copy**, for a paper-based prescription, means the duplicate of the prescription on which appear the words 'Medicare Australia/DVA copy'.

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**medicare number** has the same meaning as in Part VII of the Act.

**medication chart** has the meaning given by subregulation 19AA(4).

**medication chart prescription** has the meaning given by subregulation 19AA(1).

**optometrist** has the meaning given by subsection 84(1) of the Act.

**out-patient medication** has the same meaning as in Part VII of the Act.

**paper-based prescription** means a prescription that is prepared in duplicate in accordance with subparagraph 19(1)(a)(i), (ii) or (iii).

**participating dental practitioner** has the same meaning as in Part VII of the Act.

**PBS prescriber** has the meaning given by subsection 84(1) of the Act.

**pharmaceutical benefit** has the same meaning as in Part VII of the Act.

**pharmaceutical item** has the same meaning as in Part VII of the Act.

**pharmaceutical item has a drug** has the same meaning as in Part VII of the Act.

**pharmacist/patient copy**, for a paper-based prescription, means the original of the prescription on which appear the words 'pharmacist/patient copy'.

**price adjustment** means an adjustment under:

- (a) a price agreement; or
- (b) a price determination; or
- (c) Division 3A of Part VII of the Act.

**price sampling day**: see regulation 37D.

Regulation 5

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***public hospital*** has the same meaning as in Part VII of the Act.

***public hospital authority*** has the same meaning as in Part VII of the Act.

***ready-prepared pharmaceutical benefit*** means a pharmaceutical benefit in respect of which a determination made under subsection 85(6) of the Act is in force.

***record form*** has the same meaning as in Part VII of the Act.

***related brand***, of a brand of a pharmaceutical item, means a brand of a pharmaceutical item that has the same drug and manner of administration as the first pharmaceutical item (including another brand of the same pharmaceutical item), but does not include a brand of an exempt item.

Note: For the definition of ***exempt item***, see subsection 84(1) of the Act.

***relevant entitlement period*** has the same meaning as in Part VII of the Act.

***repatriation pharmaceutical benefit*** has the same meaning as in Part VII of the Act.

***repeat authorisation*** means a repeat authorisation prepared under subparagraph 26(1A)(a)(i).

***repeat authorisation form*** means the form mentioned in subparagraph 26 (1A)(a)(i).

***residential care*** has the meaning given by section 41–3 of the *Aged Care Act 1997*.

***residential care service*** has the same meaning as in the *Aged Care Act 1997*.

***responsible person*** has the same meaning as in Part VII of the Act.

***special patient contribution*** has the same meaning as in Part VII of the Act.

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**start day**, for a brand of a pharmaceutical item, means the day on which the brand was first required to comply with the price disclosure requirements under section 99ADD of the Act.

**the Act** means the *National Health Act 1953*.

- (2) In these Regulations, unless the contrary intention appears, a reference to prescribing or to the writing of a prescription shall be read as a reference to the writing of a prescription for the supply of a pharmaceutical benefit under Part VII of the Act.
- (3) In these Regulations, unless the contrary intention appears:
- (a) a reference to the holder of a concession card or an entitlement card shall be read as a reference to a person who is, by virtue of section 84G of the Act, to be taken to be a holder of the card;
  - (aa) a reference to the original holder of a concession card is a reference to the person to whom a concession card has been issued under section 84DA of the Act;
  - (b) a reference to the original holder of an entitlement card shall be read as a reference to the person to whom an entitlement card has been issued under section 84E of the Act; and
  - (c) a reference to a member of the family of a person shall be read as a reference to a person who is a member of that family within the meaning of section 84B of the Act.

**Part 1** Preliminary

**Division 1.2** Application of Regulations to electronic prescriptions and electronic orders

Regulation 5A

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**Division 1.2—Application of Regulations to electronic prescriptions and electronic orders**

**5A Preparing electronic prescriptions**

A reference in these Regulations to writing or preparing a prescription, a repeat authorisation or a deferred supply authorisation, whether the expression *writing, preparing* or any other expression is used, is taken to include:

- (a) for an electronic prescription—writing or preparing the prescription by means of an electronic form approved by the Secretary under sub-subparagraph 19(1)(a)(ia)(B) or subregulation 19AA(5) for the purposes of writing an electronic prescription; and
- (b) for a repeat authorisation that relates to an electronic prescription—writing or preparing the authorisation by means of an electronic form authorised by the Secretary under subparagraph 26(1A)(a)(i) for the supply of a pharmaceutical benefit under an electronic prescription; and
- (c) for a deferred supply authorisation that relates to an electronic prescription—writing or preparing the authorisation by means of an electronic form authorised by the Secretary under paragraph 26A(2)(a) for deferring the supply of a pharmaceutical benefit under an electronic prescription.

**5B Date when a prescription is written or a pharmaceutical benefit is prescribed**

A reference in these Regulations to the day or date on which a prescription is written by a PBS prescriber or the day or date on which a pharmaceutical benefit is prescribed is, in relation to an electronic prescription, the day or date on which the prescription is signed by the PBS prescriber.

### **5C Requirement to give information in writing**

- (1) If, under these Regulations, a person is required to write information on a prescription, a repeat authorisation, a deferred supply authorisation or an order form, that requirement is taken to have been met in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form, if the person gives the information:
  - (a) in accordance with approved information technology requirements (if any); and
  - (b) by means of an approved electronic communication.
- (2) This regulation applies to a requirement to write information on a prescription, a repeat authorisation, a deferred supply authorisation or an order form, whether the expression *write, certify, endorse, identify, indicate, mark, specify, state*, or any other expression is used.

### **5D Requirement to give a prescription**

If, under these Regulations, a prescription is required to be given or presented to an approved supplier for the purpose of supplying a pharmaceutical benefit to the person for whom the prescription was written, that requirement is taken to have been met in relation to an electronic prescription if:

- (a) the person who will receive the pharmaceutical benefit (whether or not for the person's own use) requests the approved supplier to supply the pharmaceutical benefit; and
- (b) the approved supplier consents, within the meaning of subsection 5(1) of the *Electronic Transactions Act 1999*, to the prescription being given or presented, in accordance with approved information technology requirements (if any), by means of an approved electronic communication; and
- (c) the prescription is accessible by the approved supplier.

**Part 1** Preliminary

**Division 1.2** Application of Regulations to electronic prescriptions and electronic orders

**Regulation 5E**

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**5E Approval of kinds of electronic communications**

The Secretary may, in writing, approve a kind of electronic communication for 1 or more of the following purposes:

- (a) preparing or submitting an electronic prescription;
- (b) giving information, for the purposes of these Regulations, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;
- (c) giving or presenting an electronic prescription to an approved supplier under these Regulations;
- (d) submitting an electronic prescription to the Minister in accordance with paragraph 13(3)(b);
- (e) lodging an order with an approved pharmacist to obtain a pharmaceutical benefit for the purpose of section 93, 93AA or 93AB of the Act;
- (f) submitting a receipt for a pharmaceutical benefit received under paragraph 16(1)(b);
- (g) giving an acknowledgment under these Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription;
- (h) doing any other thing that is required or permitted to be done for the purposes of these Regulations.

**5F Approval of information technology requirements**

The Secretary may, in writing, approve information technology requirements for 1 or more of the following purposes:

- (a) preparing and submitting an electronic prescription;
- (b) giving information, for the purposes of these Regulations, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;
- (c) giving or presenting an electronic prescription to an approved supplier under these Regulations;

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- (d) lodging an order with an approved pharmacist to obtain a pharmaceutical benefit for the purpose of section 93, 93AA or 93AB of the Act;
- (e) submitting a receipt for a pharmaceutical benefit received under paragraph 16(1)(b);
- (f) giving an acknowledgment under these Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription;
- (g) doing any other thing that is required or permitted to be done for the purposes of these Regulations.

## Part 2—Approvals under Part VII of the Act

### 8 Application for approval to be in approved form

The Minister, in the case of a hospital authority, and the Secretary, in the case of a pharmacist or medical practitioner, may refuse to entertain an application for approval under Part VII of the Act unless the application:

- (a) in the case of an application for approval of a pharmacist—is in accordance with a form approved in writing by the Secretary;
- (b) in the case of an application for approval of a hospital authority—is in accordance with a form approved in writing by the Secretary; and
- (c) in the case of an application for approval of a medical practitioner—is in accordance with a form approved in writing by the Secretary.

### 8AA Application for approval as authorised optometrist, authorised midwife or authorised nurse practitioner

The following applications must be made in a form acceptable to the Secretary:

- (a) an application for approval as an authorised optometrist under subsection 84AAB(1) of the Act;
- (b) an application for approval as an authorised midwife under subsection 84AAF(1) of the Act;
- (c) an application for approval as an authorised nurse practitioner under subsection 84AAJ(1) of the Act.

### 8A Numbering of approvals

- (1) If the Secretary approves:
  - (a) a dental practitioner under section 84A of the Act; or
  - (aa) an optometrist under section 84AAB of the Act; or

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- (ab) an eligible midwife under section 84AAF of the Act; or
  - (ac) an eligible nurse practitioner under section 84AAJ of the Act;  
or
  - (b) a pharmacist under section 90 of the Act; or
  - (c) a medical practitioner under section 92 of the Act;
- he or she may allot a number to that approval.
- (1A) If the Secretary grants permission to a person to supply pharmaceutical benefits under subsection 91(1) of the Act, he or she may allot a number to the approval that, under paragraph 91(7)(a) of the Act, is treated as having been granted to the person under section 90 of the Act.
  - (1B) If the Minister substitutes for a decision of the Secretary to which section 90A of the Act applies a decision approving a pharmacist for the purpose of supplying pharmaceutical benefits at or from particular premises, the Minister may allot a number to that approval.
  - (2) If the Minister approves a hospital authority under section 94 of the Act he or she may allot a number to that approval.

**9 Certain requirements to be met after cancellation etc of approval**

- (1) If the approval of an approved pharmacist is suspended, revoked or cancelled, the pharmacist must not, in any way, indicate that he or she has been, or is, approved to supply pharmaceutical benefits.

Penalty: 1 penalty unit.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

## Part 2B—Safety net concession cards

### 9AA Safety net concession card

- (1) For the purposes of paragraph 84DA(3)(b) of the Act, the following particulars are prescribed in relation to an application under subsection 84DA(1) or (2) of the Act:
  - (a) the full name of the applicant;
  - (b) the residential address of the applicant;
  - (c) the full name of each person who is a member of the applicant's family;
  - (d) the relationship of each person referred to in paragraph (c) to the applicant;
  - (e) the date on which the application is made;
  - (f) the medicare number of the applicant.
- (2) For the purposes of paragraph 84DA(3)(b) of the Act, the following documents are prescribed in relation to an application under subsection 84DA(1) or (2) of the Act:
  - (a) record forms issued to the applicant or to a member of the applicant's family that:
    - (i) record the value of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication supplied to the applicant, or to a member of the applicant's family, during the relevant entitlement period to which the application relates; and
    - (ii) bear a statement signed by the applicant declaring that the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication recorded in the form were so supplied;
  - (b) in respect of any other pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication so supplied, any document that establishes the value of that pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication.

**9AB Additional concession cards**

- (1) A person whose concession card has been lost, stolen, damaged or destroyed may apply for an additional concession card to the Secretary.
- (2) A person who is a holder of a concession card, other than a person referred to in subregulation (1), may apply for an additional concession card to:
  - (a) the Secretary; or
  - (b) where the original concession card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority—that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority.
- (3) An application under subregulation (1) or (2) for an additional concession card must:
  - (a) be in accordance with the form approved by the Secretary; and
  - (b) set out:
    - (i) the full name of the applicant; and
    - (ii) the residential address of the applicant; and
    - (iii) the full name of each person (other than the applicant) who is a member of the family of the original holder of the concession card and the relationship of that person to the original holder; and
    - (iv) the number (if known to the applicant) of any other concession card held by a member of the family of the original holder of the concession card; and
    - (v) if the application is made under subregulation (1)—the number (if known to the applicant) of the concession card that the applicant holds; and
    - (vi) the medicare number of the applicant; and
  - (c) be signed and dated by the applicant; and
  - (d) be accompanied by the original concession card unless the application is made under subregulation (1).

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- (4) Where, on an application to a person for the issue of an additional concession card, the person is satisfied, having regard to:
- (a) the matters contained in the application; and
  - (b) any other relevant matters;
- that an additional concession card should be issued to the applicant, the person must issue an additional concession card to the applicant.

### 9AC Replacement concession cards

- (1) An original holder of a concession card may apply for the issue of a replacement card.
- (2) An application under subregulation (1) must:
- (a) be made, in accordance with the form approved by the Secretary, to:
    - (i) the Secretary; or
    - (ii) where the original concession card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority—that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority; and
  - (b) set out:
    - (i) the full name of the applicant; and
    - (ii) the residential address of the applicant; and
    - (iii) the full name of any new family member and his or her relationship to the applicant; and
    - (iv) the medicare number of the applicant; and
  - (c) be signed and dated by the applicant; and
  - (d) be accompanied by the original concession card unless the application is made to the Secretary.
- (3) Where, on an application to a person for the issue of a replacement card, the person is satisfied, having regard to:
- (a) the matters contained in the application; and

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- (b) any other relevant matters;
- that:
- (c) the applicant is the original holder of the concession card to which the application relates; and
  - (d) each person identified in the application in accordance with subparagraph (2)(b)(iii) became, after the issue of that concession card and during the relevant entitlement period in respect of which that card was issued, a member of the original card holder's family;
- the person must issue a replacement concession card to the applicant.

**9AD Refusal to issue additional or replacement concession cards**

- (1) Where an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority makes:
  - (a) a decision under regulation 9AB refusing to issue an additional concession card; or
  - (b) a decision under regulation 9AC refusing to issue a replacement concession card;the applicant may apply to the Secretary under subregulation 9AB(2) or regulation 9AC for the issue of the additional concession card or replacement concession card, as the case requires.
- (2) Where the Secretary makes:
  - (a) a decision under regulation 9AB refusing to issue an additional concession card; or
  - (b) a decision under regulation 9AC refusing to issue a replacement concession card;the Secretary must, by notice in writing, inform the applicant of the making of, and reasons for, the decision.
- (3) A notice under subregulation (2) must include a statement to the effect:
  - (a) that an application may be made, subject to the *Administrative Appeals Tribunal Act 1975*, by or on behalf of

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a person whose interests are affected by the decision, to the Administrative Appeals Tribunal for review of the decision; and

- (b) that a person whose interests are affected by the decision may, except where subsection 28(4) of that Act applies, request a statement under section 28 of that Act.
- (4) A failure to comply with subregulation (3) in relation to a decision does not affect the validity of the decision.

### **9AE Review of decisions**

An application may be made to the Administrative Appeals Tribunal for review of a decision of the Secretary:

- (a) refusing to issue an additional concession card under regulation 9AB; or
- (b) refusing to issue a replacement concession card under regulation 9AC.

### **9AF Prescribed offices**

For subsection 84DA(5) of the Act, each office mentioned in Schedule 6 is a prescribed office.

## **Part 2C—Pharmaceutical benefits entitlement cards**

### **9A Pharmaceutical benefits prescription record forms**

- (1) For the purposes of paragraph 84D(3)(b) of the Act, the following particulars of the person to whom a record form is issued are prescribed particulars:
  - (a) the Christian or given names and the surname of the person;
  - (b) the address of the person.
- (2) For the purposes of subsection 84D(4) of the Act, the following particulars of a person who is a member of the family of a person to whom a record form is issued are prescribed particulars:
  - (a) the Christian or given names and the surname of the person;
  - (b) the relationship of the person to the person to whom the record form is issued.
- (4) For the purposes of paragraph 84D(7)(c) of the Act, the following particulars in relation to the supply of a pharmaceutical benefit or repatriation pharmaceutical benefit are prescribed:
  - (a) the code number set out in relation to that pharmaceutical benefit or repatriation pharmaceutical benefit in the Schedule of Pharmaceutical Benefits published by the Department;
  - (b) the number allotted under regulation 8A to the approval of the approved pharmacist, approved medical practitioner or approved hospital authority supplying the pharmaceutical benefit or repatriation pharmaceutical benefit;
  - (c) the maximum value of the pharmaceutical benefit or repatriation pharmaceutical benefit for safety net purposes.
- (4A) For the purposes of paragraph 84D(11)(c) of the Act, the following particulars in relation to the supply of out-patient medication are prescribed:
  - (a) particulars that identify the medication;

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- (b) particulars that identify the public hospital at which the medication was supplied;
  - (c) the applicable amount.
- (5) The maximum value of a pharmaceutical benefit for safety net purposes is:
- (a) if the price of the pharmaceutical benefit is charged under paragraph 87(2)(a), (b) or (c) of the Act:
    - (i) the price mentioned for the prescription in the relevant paragraph of subsection 87(2) of the Act as in force when the price is charged; or
    - (ii) if the price charged is less than the amount mentioned in subparagraph (i)—the amount of the price charged; or
  - (b) if the price of the pharmaceutical benefit is charged under paragraph 87(2)(e) of the Act:
    - (i) the price mentioned for the prescription in paragraph 87(2)(e) of the Act as in force when the price is charged; or
    - (ii) if the agreed price, within the meaning of subsection 84C(6) of the Act as in force when the price is charged, of the pharmaceutical benefit is less than the amount mentioned in subparagraph (i)—the amount of the agreed price; or
    - (iii) if the price charged is less than the amount mentioned in subparagraph (i) and less than the agreed price mentioned in subparagraph (ii)—the amount of the price charged.
- (6) The maximum value of a repatriation pharmaceutical benefit for safety net purposes is the amount charged for the benefit in accordance with a scheme referred to in subsection 91(1) of the *Veterans' Entitlements Act 1986*.

**9B Pharmaceutical benefits entitlement card**

- (1) For the purposes of paragraph 84E(3)(b) of the Act, the following particulars are prescribed in relation to an application under subsection 84E(1) or (2) of the Act:
  - (a) the full name of the applicant;
  - (b) the residential address of the applicant;
  - (c) the full name of each person who is a member of the applicant's family;
  - (d) the relationship of each person referred to in paragraph (c) to the applicant;
  - (e) the date on which the application is made;
  - (f) the medicare number of the applicant.
  
- (2) For the purposes of paragraph 84E(3)(b) of the Act, the following documents are prescribed in relation to an application under subsection 84E(1) or (2) of the Act:
  - (a) record forms issued to the applicant or to a member of the applicant's family that:
    - (i) record the value of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication supplied to the applicant, or to a member of the applicant's family, during the relevant entitlement period to which the application relates; and
    - (ii) bear a statement signed by the applicant declaring that the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication recorded in the forms were so supplied;
  - (b) in respect of any other pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication so supplied, any document that establishes the value of that pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication.

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### 9BA Prescribed offices

For subsection 84E(5) of the Act, each office mentioned in Schedule 6 is a prescribed office.

### 9C Additional entitlement cards

- (1) A person whose entitlement card has been lost, stolen, damaged or destroyed may apply for an additional entitlement card to the Secretary.
- (2) A person who is a holder of a entitlement card, other than a person referred to in subregulation (1), may apply for an additional entitlement card to:
  - (a) the Secretary; or
  - (b) where the original entitlement card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority—that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority.
- (3) An application under subregulation (1) or (2) for an additional entitlement card must:
  - (a) be in accordance with the form approved by the Secretary; and
  - (b) set out:
    - (i) the full name of the applicant; and
    - (ii) the residential address of the applicant; and
    - (iii) the full name of each person (other than the applicant) who is a member of the family of the original holder of the entitlement card and the relationship of that person to the original holder; and
    - (iv) the number (if known to the applicant) of any other entitlement card held by a member of the family of the original holder of the entitlement card; and

- (v) if the application is made under subregulation (1)—the number (if known to the applicant) of the entitlement card that the applicant holds; and
  - (vi) the medicare number of the applicant; and
  - (c) be signed and dated by the applicant; and
  - (d) be accompanied by the original entitlement card unless the application is made under subregulation (1).
- (4) Where, on an application to a person for the issue of an additional entitlement card, the person is satisfied, having regard to:
- (a) the matters contained in the application; and
  - (b) any other relevant matters;
- that an additional entitlement card should be issued to the applicant, the person must issue an additional entitlement card to the applicant.

### **9D Replacement entitlement cards**

- (1) An original holder of a entitlement card may apply for the issue of a replacement card.
- (2) An application under subregulation (1) must:
  - (a) be made, in accordance with the form approved by the Secretary, to:
    - (i) the Secretary; or
    - (ii) where the original entitlement card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority—that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority; and
  - (b) set out:
    - (i) the full name of the applicant; and
    - (ii) the residential address of the applicant; and
    - (iii) the full name of any new family member and his or her relationship to the applicant; and

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- (iv) the medicare number of the applicant; and
  - (c) be signed and dated by the applicant; and
  - (d) be accompanied by the original entitlement card unless the application is made to the Secretary.
- (3) Where, on an application to a person for the issue of a replacement card, the person is satisfied, having regard to:
- (a) the matters contained in the application; and
  - (b) any other relevant matters;
- that:
- (c) the applicant is the original holder of the entitlement card to which the application relates; and
  - (d) each person identified in the application in accordance with subparagraph (2)(b)(iii) became, after the issue of that entitlement card and during the relevant entitlement period in respect of which that card was issued, a member of the original card holder's family;
- the person must issue a replacement entitlement card to the applicant.

**9E Refusal to issue additional or replacement entitlement cards**

- (1) Where an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority makes:
- (a) a decision under regulation 9C refusing to issue an additional entitlement card; or
  - (b) a decision under regulation 9D refusing to issue a replacement entitlement card;
- the applicant may apply to the Secretary under subregulation 9C(2) or regulation 9D for the issue of the additional entitlement card or replacement entitlement card, as the case requires.
- (2) Where the Secretary makes:
- (a) a decision under regulation 9C refusing to issue an additional entitlement card; or
  - (b) a decision under regulation 9D refusing to issue a replacement entitlement card;

the Secretary must, by notice in writing, inform the applicant of the making of, and reasons for, the decision.

- (3) A notice under subregulation (2) must include a statement to the effect:
- (a) that an application may be made, subject to the *Administrative Appeals Tribunal Act 1975*, by or on behalf of a person whose interests are affected by the decision, to the Administrative Appeals Tribunal for review of the decision; and
  - (b) that a person whose interests are affected by the decision may, except where subsection 28(4) of that Act applies, request a statement under section 28 of that Act.
- (4) A failure to comply with subregulation (3) in relation to a decision does not affect the validity of the decision.

### **9F Review of decisions**

An application may be made to the Administrative Appeals Tribunal for review of a decision of the Secretary:

- (a) refusing to issue an additional entitlement card to a person under regulation 9C; or
- (b) refusing to issue a replacement entitlement card to a person under regulation 9D.

## Part 3—Pharmaceutical benefits

### 13 Variation of application of determination of maximum number of repeats or maximum number or quantity of units

- (1) For subsection 85A(3) of the Act, the Minister may vary the application of a determination under paragraph 85A(2)(a) or (b) of the Act in relation to a practitioner in the class covered by subregulation (2).
- (2) A practitioner is in the class covered by this subregulation if:
  - (a) the practitioner has written a prescription, in accordance with regulation 19 or 19AA (disregarding paragraphs 19(1)(b) and 19AA(3)(a) to (c)), that:
    - (i) is not in accordance with a determination mentioned in subregulation (1); and
    - (ii) in the case of a medication chart prescription—is written for a person who is receiving treatment in or at an approved hospital; and
  - (b) the prescription is submitted to the Minister in accordance with subregulation (3).
- (3) A prescription is submitted in accordance with this subregulation if:
  - (a) the practitioner, or an employee of the practitioner, submits:
    - (i) the prescription itself; or
    - (ii) for a medication chart prescription that is not an electronic prescription—the medication chart by which the prescription was written, or a copy of so much of that chart as would indicate that subregulation 19AA(2) has been complied with; or
  - (b) the practitioner submits details of the prescription:
    - (i) by telephone; or
    - (ii) by means of an approved electronic communication.

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- (5) A variation under subregulation (1) in relation to a practitioner may be made:
- (a) for a paper-based prescription (other than a prescription submitted in accordance with paragraph (3)(b))—by the Minister signing his or her authorisation of the prescription on it and:
    - (i) if the Minister requires the practitioner to alter the prescription—by returning it to the practitioner for alteration before the practitioner gives it to the person in respect of whom it was prepared; or
    - (ii) by returning it to the practitioner; or
    - (iii) if requested by the practitioner—by sending it to the person in respect of whom it was written; or
  - (aaa) for a medication chart prescription (other than an electronic prescription or a prescription submitted in accordance with paragraph (3)(b))—by the Minister:
    - (i) signing his or her authorisation of the prescription on the medication chart, or the copy of the medication chart, submitted in accordance with subparagraph (3)(a)(ii); and
    - (ii) if the Minister requires the practitioner to alter the prescription—indicating this on the medication chart or copy; and
    - (iii) returning the medication chart or copy to the practitioner; or
  - (aa) for an electronic prescription (other than a prescription submitted in accordance with paragraph (3)(b))—by the Minister writing his or her authorisation of the prescription on the electronic prescription and:
    - (i) if the Minister requires the practitioner to alter the prescription—by returning it, including by means of an electronic communication, to the practitioner for alteration; or
    - (ii) by returning it, including by means of an electronic communication, to the practitioner; or

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- (iii) if requested by the practitioner—by making the prescription accessible by the person in respect of whom it was written, or by an approved supplier for the purpose of supplying a pharmaceutical benefit to the person in respect of whom the prescription was written; or
  - (b) if a prescription is submitted in accordance with subparagraph (3)(b)(i) by telephone—by the Minister authorising the prescription orally, at the time the Minister is given details of the prescription; or
  - (c) if a prescription is submitted in accordance with subparagraph (3)(b)(ii) by means of an electronic communication—by the Minister sending his or her authorisation of the prescription, by electronic communication, to the practitioner.
- (6) If the Minister makes a variation in accordance with paragraph (5)(b) or (c):
  - (a) the Minister must tell the practitioner, orally or by electronic communication, the number that has been allotted to the authorised prescription; and
  - (b) the practitioner must:
    - (i) mark that number on the prescription; and
    - (ii) retain the prescription, or a copy of the prescription showing the number marked in accordance with subparagraph (i), for 1 year from the date on which the variation was made.
- (7) For subparagraph (6)(b)(ii), the date on which the Minister makes a variation in relation to a person in respect of whom a practitioner submits an electronic prescription is:
  - (a) for a variation in accordance with paragraph (5)(b)—the date on which the Minister tells the practitioner the number that has been allotted to the authorised prescription; and
  - (b) for a variation in accordance with paragraph (5)(c)—the date on which the Minister sends, by means of an electronic

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communication, his or her authorisation of the prescription to the practitioner.

(8) In this regulation:

***practitioner*** means any of the following:

- (a) an authorised optometrist;
- (b) a medical practitioner;
- (c) an authorised midwife;
- (d) an authorised nurse practitioner.

## **Part 4—Supply of pharmaceutical benefits by particular PBS prescribers**

### **14 Meaning of *practitioner***

In this Part:

*practitioner* means any of the following:

- (a) a medical practitioner;
- (b) an authorised midwife;
- (c) an authorised nurse practitioner.

### **15 Prescriber bag supplies—practitioners on ships**

A practitioner who is practising his or her profession on a ship is not authorised to supply pharmaceutical benefits under section 93, 93AA or 93AB of the Act.

### **16 Prescriber bag supplies—obtaining benefits by practitioners**

- (1) For sections 93, 93AA and 93AB of the Act, a practitioner who is not an approved medical practitioner may obtain a pharmaceutical benefit only if he or she lodges with an approved pharmacist:
  - (a) an order, in duplicate, signed by the practitioner, in accordance with a form approved in writing by the Secretary;  
or
  - (b) an order, in accordance with subregulation (1A), that is:
    - (i) signed by the practitioner; and
    - (ii) in accordance with an electronic form approved in writing by the Secretary.
- (1A) For paragraph (1)(b), an order is lodged with an approved pharmacist if:

- (a) it is lodged in accordance with any approved information technology requirements and by an approved electronic communication; and
  - (b) the practitioner, or an agent of the practitioner, who will receive the pharmaceutical benefit asks the approved pharmacist to supply the pharmaceutical benefit under the order; and
  - (c) the approved pharmacist consents, within the meaning of subsection 5(1) of the *Electronic Transactions Act 1999*, to the order being lodged, in accordance with any approved information technology requirements and by an approved electronic communication; and
  - (d) the order is accessible by the approved pharmacist.
- (2) A practitioner who is not an approved medical practitioner may obtain a pharmaceutical benefit under subregulation (1) only once in a calendar month.
- (3) A practitioner, or an agent of a practitioner, who receives a pharmaceutical benefit under subregulation (1), must:
- (a) prepare a receipt for the benefit supplied, using the part of the order form identified for that purpose, that includes the following information:
    - (i) the date of supply of the benefit;
    - (ii) if the benefit is received by an agent of the practitioner—the agent’s address; and
  - (b) if the order is lodged in accordance with paragraph (1)(a)—give the receipt to the approved pharmacist supplying the benefit; and
  - (c) if the order is lodged in accordance with paragraph (1)(b):
    - (i) submit the receipt, in accordance with any approved information technology requirements and by an approved electronic communication; and
    - (ii) ensure the receipt is accessible by the approved pharmacist supplying the benefit.

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**17 Prescriber bag supplies—supply of pharmaceutical benefits by approved pharmacists**

- (1) An approved pharmacist commits an offence if:
- (a) he or she supplies a pharmaceutical benefit on an order lodged under regulation 16; and
  - (b) neither of the following circumstances applies:
    - (i) the pharmacist knows the practitioner whose signature appears on the order;
    - (ii) if he or she does not know the practitioner, the pharmacist:
      - (A) is given the full name and address of the practitioner by the person who lodged the order; and
      - (B) if the practitioner is a medical practitioner—is given the medical registration number of the practitioner by the person who lodged the order; and
      - (C) for any other practitioner—is given the number allotted to the approval for the practitioner by the Secretary under subregulation 8A(1) by the person who lodged the order; and
      - (D) writes on the order form the details mentioned in sub-subparagraphs (A), (B) and (C).

Penalty: 0.4 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

**18 Prescriber bag supplies—payment for pharmaceutical benefits**

- (1) An approved pharmacist who supplies a pharmaceutical benefit to a practitioner on an order under regulation 16 is entitled to be paid by the Commonwealth for the supply the sum of:
- (a) the Commonwealth price of the pharmaceutical benefit; and

- (b) the special patient contribution for a brand of the pharmaceutical item that is the pharmaceutical benefit (if any).
- (2) Payment by the Commonwealth under subregulation (1) is subject to the conditions set out in a determination under paragraph 98C(1)(b) of the Act that is in force at the time the benefit is supplied, as if the benefit had been supplied other than under section 93, 93AA, or 93AB of the Act.

**18A Benefits obtained by approved medical practitioners for the purposes of section 93**

*Offence—obtaining pharmaceutical benefit for purposes of section 93 of the Act by lodging order under regulation 16*

- (1) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purpose of section 93 of the Act by lodging with an approved pharmacist an order under regulation 16.

Penalty: 0.2 penalty units.

*Offence—obtaining pharmaceutical benefit for purposes of section 93 of the Act more than once each month*

- (2) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purpose of section 93 of the Act more than once in each month.

Penalty: 0.2 penalty units.

*Offence—not giving notice of obtaining pharmaceutical benefit for purposes of section 93 of the Act (manual claim)*

- (3) An approved medical practitioner commits an offence if he or she:
  - (a) obtains a pharmaceutical benefit for the purpose of the supply of the benefit under section 93 of the Act; and

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- (b) makes a claim for a payment under section 99AAA of the Act, in relation to obtaining the benefit for such a supply, using the manual system referred to in that section; and
- (c) does not, when making the claim, give notice to the Secretary that he or she has obtained the benefit.

Penalty: 0.2 penalty units.

- (4) For subregulation (3), the notice must be:
  - (a) in a form authorised by the Secretary; and
  - (b) signed and dated by the practitioner.
- (5) An approved medical practitioner who gives a notice to the Secretary under subregulation (3) must retain a copy of the notice for at least 2 years from the date on which he or she gives the notice to the Secretary.

Penalty: 0.2 penalty units.

*Offence—not creating record of obtaining pharmaceutical benefit for purposes of section 93 of the Act (CTS claim)*

- (5A) An approved medical practitioner commits an offence if he or she:
  - (a) obtains a pharmaceutical benefit for the purpose of the supply of the benefit under section 93 of the Act; and
  - (b) makes a CTS claim in relation to obtaining the benefit for such a supply; and
  - (c) does not create a written record of having obtained the benefit as soon as practicable after obtaining it.

Penalty: 0.2 penalty units.

- (5B) For subregulation (5A), the record must be:
  - (a) in a form authorised by the Secretary; and
  - (b) signed and dated by the practitioner.
- (5C) An approved medical practitioner who creates a record under subregulation (5A) must retain the record for at least 2 years from the date on which it was created.

Penalty: 0.2 penalty units.

*Strict liability applies to offences*

- (6) An offence against subregulation (1), (2), (3), (5), (5A) or (5C) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

*Entitlement to payment*

- (7) An approved medical practitioner is entitled to payment from the Commonwealth for obtaining a pharmaceutical benefit for the purpose of the supply of the benefit under section 93 of the Act if:
- (a) the pharmaceutical benefit is obtained in accordance with these Regulations; and
  - (b) the approved medical practitioner makes a claim for a payment under section 99AAA of the Act in relation to obtaining the benefit for such a supply; and
  - (c) if the claim is made using the manual system referred to in that section—the approved practitioner gives a notice to the Secretary in accordance with subregulation (3).
- (8) The approved medical practitioner is entitled to payment under subregulation (7) at the rate applicable under regulation 18 for the supply of the same benefit on an order under regulation 16.

## **Part 5—Prescriptions and supply**

### **18B Purpose of Part**

- (1) Unless otherwise specified, this Part is made for section 105 of the Act.
- (2) This Part:
  - (a) prescribes terms and conditions relating to the supply of pharmaceutical benefits; and
  - (b) provides rules about writing prescriptions.

### **18C Writing prescriptions—general**

A prescription for the supply of a pharmaceutical benefit must be written in accordance with:

- (a) regulation 19 (prescriptions other than medication chart prescriptions); or
- (b) regulation 19AA (medication chart prescriptions).

Note: Other provisions of these Regulations may also contain requirements for the writing of prescriptions.

### **19 Writing prescriptions—prescriptions other than medication chart prescriptions**

- (1) A PBS prescriber writes a prescription in accordance with this regulation if the PBS prescriber:
  - (a) prepares the prescription:
    - (i) in duplicate, by handwriting the prescription in ink on a prescription form:
      - (A) that is as nearly as practicable 18 centimetres long by 12 centimetres wide; and
      - (B) on which appears the name and address of the PBS prescriber and, subject to subregulation (4), the letters ‘PBS’; and

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- (C) on the original of which appear the words ‘pharmacist/patient copy’; and
- (D) on the duplicate of which appear the words ‘Medicare Australia/DVA copy’; or
- (ii) in duplicate, by means of a computer on a prescription form:
  - (A) that is as nearly as practicable 18 centimetres long by 12 centimetres wide; and
  - (B) on which appears the name and address of the PBS prescriber and, subject to subregulation (4), the letters ‘PBS’; and
  - (C) on the original of which appear the words ‘pharmacist/patient copy’; and
  - (D) on the duplicate of which appear the words ‘Medicare Australia/DVA copy’; and
  - (E) that is approved in writing for the purpose by the Secretary; or
- (iia) by means of a form:
  - (A) on which appear the name and address of the PBS prescriber and the letters ‘PBS’; and
  - (B) that is approved in writing by the Secretary for the purpose of writing an electronic prescription; or
- (iii) by another method approved in writing by the Secretary; and
- (aa) signs the prescription after it is prepared; and
- (b) for an authority prescription other than an authority prescription mentioned in subregulation (6)—writes on it:
  - (i) each authority approval number allotted by the Minister or the Chief Executive Medicare for the prescription, unless the prescription is to be posted or delivered to the Minister or Chief Executive Medicare for authorisation; or
  - (ii) the streamlined authority code that is part of:

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- (A) the circumstances determined by the Minister under paragraph 85(7)(b) of the Act for the pharmaceutical benefit that is prescribed; or
  - (B) the conditions determined by the Minister under subsection 85A(2A) of the Act for the pharmaceutical benefit that is prescribed; and
  - (c) specifies on the prescription the date on which the prescription is written; and
  - (ca) for a participating dental practitioner, authorised optometrist, authorised midwife or authorised nurse practitioner—states in the prescription the number allotted to his or her approval under regulation 8A; and
  - (d) states in the prescription the name of the person for whom the pharmaceutical benefit is to be supplied and the address of that person; and
  - (e) identifies in the prescription the pharmaceutical benefit by such particulars as are necessary to identify the pharmaceutical benefit; and
  - (f) states in the prescription:
    - (i) the quantity or number of units of the pharmaceutical benefit to be supplied; and
    - (ii) if the supply of the benefit is to be repeated—the number of times it is to be repeated; and
  - (g) if the pharmaceutical benefit to be supplied is not a ready-prepared pharmaceutical benefit—indicates in the prescription the manner in which the pharmaceutical benefit is to be administered; and
  - (h) if, under regulation 24, the medical practitioner, authorised midwife or authorised nurse practitioner directs in the prescription the supply on the one occasion of a quantity or number of units of a pharmaceutical benefit exceeding the quantity or number of units that could otherwise be prescribed—writes on the prescription ‘Reg 24’ or ‘Regulation 24’.
- (2) A prescription written in accordance with this regulation must not provide for the supply of a pharmaceutical benefit to:

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- (a) a person if the PBS prescriber has written, on the same day, another prescription for the supply of the same or an equivalent pharmaceutical benefit to the person; or
  - (b) more than 1 person.
- (4) For the purposes of sub-subparagraphs (1)(a)(i)(B) and (1)(a)(ii)(B), a prescription form that was printed before 1 June 1996 may contain the letters ‘NHS’ instead of the letters ‘PBS’.
- (5) For subparagraphs (1)(a)(ii), (iia) and (iii), a prescription must not be prepared using a computer program that operates, or may operate, to indicate on a prescription by default, for the purpose of subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied.
- (6) Paragraph (1)(b) does not apply to authority prescriptions that have been authorised in accordance with authority required procedures that are incorporated by reference into the circumstances determined for a pharmaceutical benefit under subsection 85B(4) of the Act.

Note: If a streamlined authority code or an authority approval number must be written on an authority prescription, and the code or number is not written on the authority prescription, the special patient contribution mentioned in subsection 85B(4) of the Act is not payable by the Commonwealth: see subsection 85B(5) of the Act.

**19AA Writing prescriptions—medication chart prescriptions***Writing prescription by completing section of medication chart*

- (1) A PBS prescriber writes a prescription (a **medication chart prescription**) for a pharmaceutical benefit in accordance with this regulation if:
- (a) the person for whom the pharmaceutical benefit is prescribed is receiving treatment in or at:
    - (i) a residential care service at which the person is receiving residential care; or
    - (ii) an approved hospital; and

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- (b) the PBS prescriber completes a section of a medication chart for the person in relation to the pharmaceutical benefit in accordance with:
  - (i) subregulation (2); and
  - (ii) if the prescription would be an authority prescription—subregulation (3).

*Completing section of medication chart—general*

- (2) A PBS prescriber completes a section of a medication chart in accordance with this subregulation for a person (the *patient*) in relation to a pharmaceutical benefit if:
  - (a) the PBS prescriber writes in the section of the chart:
    - (i) particulars sufficient to identify the pharmaceutical benefit; and
    - (ii) the date on which the pharmaceutical benefit is prescribed; and
    - (iii) the pharmaceutical benefit's dose, frequency of administration and route of administration; and
    - (iv) the letters "PBS" or "RPBS"; and
  - (b) the chart contains the following information:
    - (i) the PBS prescriber's full name, address and PBS prescriber number;
    - (ii) the patient's full name;
    - (iii) the name of the residential care service or approved hospital in or at which the patient is receiving treatment;
    - (iv) if the patient is receiving treatment in or at a residential care service—the Residential Aged Care Service ID for the residential care service;
    - (v) if the patient is receiving treatment in or at an approved hospital—the patient's address; and
  - (c) the PBS prescriber writes his or her signature:
    - (i) in the section of the chart; and
    - (ii) except in the case of an electronic prescription—on the cover page of the chart; and

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- (d) the section of the chart does not provide for the supply of a pharmaceutical benefit to more than one person; and
- (e) the section of the chart is not completed using a computer program that operates, or may operate, to indicate on a prescription by default, for subsection 103(2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied; and
- (f) if the patient is receiving treatment in or at an approved hospital—the chart specifies the day on which the chart’s period of validity ends under subregulation 21A(3A), which must be the last day of one of the following periods starting on the day the first prescription for a pharmaceutical benefit is written in the chart:
  - (i) 1 month;
  - (ii) 4 months;
  - (iii) 12 months; and
- (g) if the patient is receiving treatment in or at a residential care service—the pharmaceutical benefit is not mentioned in Schedule 8 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989*); and
- (h) in any case—the section of the chart is completed before the end of the chart’s period of validity under subregulation 21A(3) or (3A).

Note: A section in a medication chart may set out fields that only need to have information filled in if the information is relevant to the particular prescription concerned.

Example: For paragraph (f), the first prescription is written in a medication chart on 11 June in a particular year. The day specified in the chart as the day on which the chart’s period of validity ends must be 10 July or 10 October in that year, or 10 June in the following year.

*Completing section of medication chart—authority prescriptions*

- (3) A PBS prescriber completes a section of a medication chart in accordance with this subregulation for a person for the purpose of writing an authority prescription if the section of the chart contains:

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- (a) each streamlined authority code (if any) that is part of the circumstances determined under paragraph 85(7)(b) of the Act for the pharmaceutical benefit that apply in relation to the writing of the prescription; and
- (b) each streamlined authority code (if any) that is part of the conditions determined under subsection 85A(2A) of the Act for the pharmaceutical benefit that apply in relation to the writing of the prescription; and
- (c) if the person is receiving treatment in or at a hospital—each authority approval number (if any) allotted by the Minister or Chief Executive Medicare for the prescription.

### *Medication charts*

- (4) A **medication chart** is a chart in a form (if any) approved under subregulation (5) that is used for prescribing, and recording the administration of, pharmaceutical benefits to persons receiving treatment in or at a residential care service or a hospital, whether or not the chart:
  - (a) is used for any other purpose; or
  - (b) contains any other information.

Note: For paragraph (a), the chart may also be used (for example) to prescribe, and record the administration of, drugs, medicines and other substances that are not pharmaceutical benefits.

- (5) The Secretary may, in writing, approve one or more forms for the purposes of subregulation (4), including one or more forms for the purpose of writing an electronic prescription.

## **19A Information about status of person**

- (1A) This regulation does not apply in relation to a medication chart prescription.

Note: See regulation 21C for information about the status of a person for a medication chart prescription, and for a continued dispensing supply under section 89A of the Act.

- (1) For the purposes of subsections 84AA(1), (1A), (2) and (3) of the Act, the following information is prescribed:

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- (a) in relation to a person who is a concessional beneficiary:
    - (i) information that the person is a concessional beneficiary; and
    - (ii) the number specified on a card held by the person (being a card issued by the Commonwealth) as being an entitlement number (however described) in relation to the person;
  - (b) in relation to a person who is a holder of a concession card:
    - (i) information that the person is the holder of a concession card; and
    - (ii) the number of the card;
  - (ba) in relation to a person who is a holder of an entitlement card:
    - (i) information that the person is the holder of an entitlement card; and
    - (ii) the number of the card;
  - (c) in relation to a person who is a dependant of a concessional beneficiary:
    - (i) information that the person is a dependant of a concessional beneficiary; and
    - (ii) the number specified on a card held by that concessional beneficiary (being a card issued by the Commonwealth) as being an entitlement number (however described) in relation to the person.
- (2) For the purposes of subsections 84AA(1) and (1A) of the Act, prescribed information shall be written or marked on a prescription by making:
- (a) in accordance with a form approved by the Secretary for the purposes of this subregulation, provision on the prescription for the supply of that information; or
  - (b) where the Minister has, by notice in writing published in the *Gazette*, given his or her consent to that effect—an endorsement on the prescription in a form that, immediately before the commencement of this regulation, was a prescribed form for the purposes of section 84AA of the Act as then in force;

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and inserting:

- (c) in the case of information that the person to whom the prescription relates is a concessional beneficiary or a dependant of a concessional beneficiary—a tick or a cross in the square provided on the prescription for the supply of such information in relation to the person;
  - (da) in the case of information that the person to whom the prescription relates is a holder of a concession card or an entitlement card—a tick or a cross in the square provided on the prescription for the supply of such information in relation to the person; and
  - (e) in a case where the information is the entitlement number referred to in subparagraph (1)(a)(ii), (1)(b)(ii), (1)(ba)(ii) or (1)(c)(ii) (as the case may be) in relation to the person to whom the prescription relates—the letters and digits forming that number, in the appropriate sequence, in the squares provided on the prescription for the supply of such information.
- (2A) For a prescription to which subsection 84AA(1) or (1A) of the Act applies, subregulations (1) and (2) do not apply if:
- (a) the claim for a payment from the Commonwealth in relation to the supply of the pharmaceutical benefit to which the prescription relates is made under the Claims Transmission System, within the meaning of section 99AAA of the Act; and
  - (b) the claim includes the card number that, under subregulation (1) would, except for this subregulation, be required.
- (3) For the purposes of subsections 84AA(2) and (3) of the Act, prescribed information shall be communicated to a pharmacist orally or in writing.

### **19B Restriction on using PBS and NHS forms**

- (1) A person commits an offence if:

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- (a) he or she writes a prescription on a form bearing the letters 'PBS', 'NHS' or 'N. H. S'; and
- (b) the prescription is not written in accordance with, or for a purpose authorised by, these Regulations; and
- (c) the letters 'PBS', 'NHS' or 'N. H. S' (as the case may be) are not clearly struck out, or obliterated.

Penalty: 0.4 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

## **21 Supply of pharmaceutical benefit on first presentation of prescription**

- (1A) This regulation does not apply in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

Note: See regulation 21A.

- (1) A pharmaceutical benefit may only be supplied on the basis of a medication chart prescription by:
  - (a) if the person in respect of whom the pharmaceutical benefit is to be supplied is receiving treatment in or at a residential care service—an approved pharmacist or an approved medical practitioner; or
  - (b) if the person in respect of whom the pharmaceutical benefit is to be supplied is receiving treatment in or at an approved hospital—an approved pharmacist or the approved hospital authority.
- (2) An approved hospital authority must not supply a pharmaceutical benefit to a person on the first presentation of a prescription for the supply of that benefit to that person, unless:
  - (a) subject to regulations 22, 26 and 26A, the prescription is:
    - (i) written in accordance with these Regulations; and
    - (ii) given to the pharmacist or practitioner; and

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- (aa) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written; and
- (b) the prescription (including, for a paper-based prescription, both the original and the duplicate) is marked, for the hospital authority, with:
  - (i) the hospital authority's name and approval number under regulation 8A; and
  - (ii) a number that identifies the prescription.
- (3) In this regulation, a reference to the first presentation of a prescription is taken to mean, in relation to an electronic prescription, the first occasion when the prescription is accessed by an approved pharmacist or an approved medical practitioner for the purpose of supplying a pharmaceutical benefit to the person for whom the prescription was written.

### **21A Supply of pharmaceutical benefit on basis of medication chart prescription**

- (1) A pharmaceutical benefit may only be supplied on the basis of a medication chart prescription by:
  - (a) if the person in respect of whom the pharmaceutical benefit is to be supplied is receiving treatment in or at a residential care service—an approved pharmacist or an approved medical practitioner; or
  - (b) if the person in respect of whom the pharmaceutical benefit is to be supplied is receiving treatment in or at an approved hospital—an approved pharmacist or the approved hospital authority.
- (2) An approved supplier may supply a pharmaceutical benefit on the basis of a medication chart prescription only if:
  - (a) the approved supplier has seen:
    - (i) the medication chart by which the prescription was written; or

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- (ii) a copy of so much of the chart as would indicate that subregulation 19AA(2), and subregulation 19AA(3) (if applicable), have been complied with; and
  - (c) the date on which the pharmaceutical benefit is supplied is:
    - (i) during the period of validity of the medication chart; and
    - (ii) no later than the stop date (if any) indicated in the prescription; and
  - (d) the approved supplier writes on the medication chart, or the copy of the chart, the following for the supply:
    - (i) the approved supplier's name and approval number under regulation 8A;
    - (ii) an identification number for the supply;
    - (iii) the date on which the pharmaceutical benefit is supplied.
- (3) For paragraph (2)(c), the period of validity of a medication chart for a person receiving treatment in or at a residential care service:
- (a) starts on the day in a calendar month (the ***first calendar month***) when the first prescription for a pharmaceutical benefit is written in the medication chart; and
  - (b) ends on the last day of the third calendar month that starts after the first calendar month.
- Example: The first prescription is written in a medication chart on 11 June. The period of validity of the medication chart starts on 11 June and ends on 30 September.
- Note: ***calendar month*** is defined in section 2B of the *Acts Interpretation Act 1901*.
- (3A) For paragraph (2)(c), the period of validity of a medication chart for a person receiving treatment in or at a hospital:
- (a) starts on the day when the first prescription for a pharmaceutical benefit is written in the chart; and
  - (b) ends at the end of the day specified in the chart as the day on which the chart's period of validity ends (see paragraph 19AA(2)(f)).

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- (4) An approved supplier may supply up to a maximum quantity of a pharmaceutical item or pharmaceutical benefit more than once on the basis of a particular medication chart prescription for the pharmaceutical benefit only if:
- (a) the prescription indicates that an ongoing supply of the pharmaceutical benefit is authorised for the period of validity of the chart; or
  - (b) the prescription indicates a stop date for the supply of the pharmaceutical benefit and, based on the dose and frequency of administration of the pharmaceutical benefit indicated in the prescription, more than one supply of a maximum quantity of the pharmaceutical item or pharmaceutical benefit is needed before the stop date is reached.

Note: See paragraph 85A(2)(a) of the Act in relation to maximum quantities of pharmaceutical items or pharmaceutical benefits.

- (5) If paragraphs (4)(a) and (b) do not apply, an approved supplier may only supply the quantity of the pharmaceutical benefit needed to give effect to the prescription, up to a maximum quantity of the pharmaceutical item or pharmaceutical benefit.

Note: The following information entered in the prescription may also indicate the quantity of the pharmaceutical benefit that is needed:

- (a) the dose and frequency of administration of the pharmaceutical benefit;
- (b) the date of prescribing, or the start date (if any) for administration of the pharmaceutical benefit;
- (c) the stop date (if any) for administration of the pharmaceutical benefit.

- (6) However, for a supply:
- (a) on the basis of a prescription mentioned in paragraph (4)(a); or
  - (b) mentioned in subregulation (5);
- an approved supplier may supply up to a maximum quantity of the pharmaceutical item or pharmaceutical benefit even if the period of validity of the medication chart will end before administration of that quantity in accordance with the prescription would finish.

**21B Continued dispensing supply of pharmaceutical benefit**

- (1) This regulation applies in relation to the supply of a pharmaceutical benefit to a person by an approved pharmacist under subsection 89A(1) of the Act.
- (2) The approved pharmacist must not supply the pharmaceutical benefit unless the approved pharmacist writes on a repeat authorisation form for the supply:
  - (a) the approved pharmacist's name and approval number under regulation 8A; and
  - (b) an identification number for the supply; and
  - (c) the date on which the pharmaceutical benefit is supplied by the approved pharmacist.

**21C Information about status of person—continued dispensing and medication chart prescriptions**

- (1) This regulation applies in relation to:
  - (a) the supply of a pharmaceutical benefit to a person (the *patient*) by an approved pharmacist (the *supplier*) under subsection 89A(1) of the Act; and
  - (b) the supply of a pharmaceutical benefit by an approved supplier (the *supplier*) on the basis of a medication chart prescription written for a person (the *patient*).
- (2) The supplier must collect the following information at the time of supply:
  - (a) information about whether the patient is, at the time of the supply:
    - (i) a concessional beneficiary or a dependant of a concessional beneficiary; or
    - (ii) the holder of a concession card or entitlement card;
  - (b) for a person mentioned in subparagraph (a)(i)—the number specified on a card, issued by the Commonwealth, as an entitlement number (however described) in relation to the person;

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- (c) for a person mentioned in subparagraph (a)(ii)—the number of the concession card or entitlement card.
- (3) The supplier must include the information collected under subregulation (2) in the claim for a payment from the Commonwealth in relation to the supply using the Claims Transmission System, within the meaning given by subsection 99AAA(1) of the Act.

**22 Supply of pharmaceutical benefits before surrender of written prescription**

- (1) Subject to this regulation, a pharmaceutical benefit may be supplied to a person, in a case of urgency, by an or an approved medical practitioner (the *supplier*) before the prescription for that pharmaceutical benefit is given to the supplier if:
  - (a) a PBS prescriber advises the supplier of the details of the prescription; or
  - (b) the PBS prescriber has given the supplier a copy of the prescription.
- (2) If the prescription is or would be an authority prescription, the supplier may supply the pharmaceutical benefit under subregulation (1) only if:
  - (a) the Minister or the Chief Executive Medicare has notified the PBS prescriber (orally or by other means) that each relevant authorisation will be given; and
  - (b) the PBS prescriber informs the supplier of that notification before the pharmaceutical benefit is supplied.
- (3) A PBS prescriber referred to in subregulation (1) must ensure that, for a paper-based prescription, the original and a duplicate of the prescription are received by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

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- (3AA) A PBS prescriber referred to in subregulation (1) must ensure that, for an electronic prescription, the prescription is accessible by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

- (3A) An offence against subregulation (3) or (3AA) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

- (4) A PBS prescriber who has communicated with an approved pharmacist or approved medical practitioner under subregulation (2) must ensure that, for a paper-based prescription, the original and a duplicate of the prescription are received by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

- (4AA) A PBS prescriber who has communicated with an approved pharmacist or approved medical practitioner under subregulation (2) must ensure that, for an electronic prescription, the prescription is accessible by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

- (4A) An offence against subregulation (4) or (4AA) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

- (5) This regulation does not apply to:
- (a) a pharmaceutical benefit if:
    - (i) the pharmaceutical benefit would be supplied under this regulation by an approved pharmacist; and
    - (ii) the relevant prescription must be in writing under a law in force in the State or Territory in which the premises,

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- at or from which the pharmaceutical benefit would be supplied, are located; or
- (b) a pharmaceutical benefit if:
    - (i) the pharmaceutical benefit would be supplied under this regulation by an approved medical practitioner; and
    - (ii) the relevant prescription must be in writing under a law in force in the area in respect of which the medical practitioner is approved; or
  - (c) in any case—a pharmaceutical benefit to be supplied on the basis of a medication chart prescription.

### **24 Circumstances in which quantity of repeated supply can be directed to be supplied on one occasion**

- (1) A medical practitioner may, in pursuance of subsection 88 (6) of the Act, instead of directing a repeated supply of a pharmaceutical benefit in accordance with Part VII of the Act, direct in a prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit allowable under that subsection if he or she is satisfied that:
  - (a) the maximum quantity or number of units applicable in relation to the pharmaceutical benefit under a determination of the Minister under section 85A of the Act is insufficient for the medical treatment of the person for whom the prescription is written; and
  - (b) that person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to that person's place of residence; and
  - (c) that person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions.
- (2) For subsection 88(6B) of the Act, an authorised midwife or authorised nurse practitioner may, instead of directing a repeated supply, direct in a prescription the supply on one occasion of a

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quantity or number of units of the pharmaceutical benefit allowable under subsection 88(6A) of the Act if he or she is satisfied that:

- (a) the maximum quantity or number of units applicable for the pharmaceutical benefit under a determination under section 85A and subsection 88(1D) or (1E) of the Act is insufficient for the treatment of the person for whom the prescription is written; and
  - (b) the person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to the person's place of residence; and
  - (c) the person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions.
- (3) However, this regulation does not apply in relation to the writing of a medication chart prescription.

**24A Continued dispensing—repeated supply not to be supplied on one occasion**

- (1) This regulation applies in relation to the supply (the *continued dispensing supply*) of a pharmaceutical benefit by an approved pharmacist under subsection 89A(1) of the Act on the basis of a previous prescription from a PBS prescriber.
- (2) If the PBS prescriber directed in the prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit allowable under subsection 88(6) of the Act, instead of directing a repeated supply, the direction does not apply for the purposes of the continued dispensing supply.

**25 Repeated supplies of pharmaceutical benefits**

- (1) A pharmaceutical benefit shall not be supplied a number of times greater than the number specified in the prescription.
- (2) Subregulation (3) applies to a pharmaceutical benefit in relation to which:

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- (a) the Minister determines, under paragraph 85A(2)(b) of the Act, that the maximum number of occasions on which the supply of the benefit may, in one prescription, be directed to be repeated is more than 4; and
  - (b) the Minister determines, under paragraph 85A(2)(c) of the Act, that the manner of administration that may, in a prescription, be directed to be used in relation to the benefit is administration otherwise than by application to the eye.
- (3) A pharmaceutical benefit to which this subregulation applies may be supplied to the person in respect of whom the prescription for the supply of the benefit was written if:
- (a) the supplier of the benefit reasonably believes that the person has not received a supply of the pharmaceutical benefit, or of another brand of that benefit, in the period of 20 days immediately preceding the day on which it is to be supplied to the person; or
  - (b) the supplier of the benefit:
    - (i) reasonably believes that a supply of the pharmaceutical benefit that was previously supplied to the person has been destroyed, lost or stolen; and
    - (ii) writes the words ‘immediate supply necessary’:
      - (A) for a paper-based prescription—on the Medicare Australia/DVA copy; or
      - (B) for an electronic prescription—on the prescription; and
    - (iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires; or
  - (c) the supplier of the benefit:
    - (i) reasonably believes that, having regard to the person’s circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person; and
    - (ii) writes the words ‘immediate supply necessary’:
      - (A) for a paper-based prescription—on the Medicare Australia/DVA copy; or

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- (B) for an electronic prescription—on the prescription; and
  - (iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires.
- (4) A pharmaceutical benefit other than a benefit to which subregulation (3) applies may be supplied to the person in respect of whom the prescription for the supply of the benefit was written if:
  - (a) the supplier of the benefit reasonably believes that the person has not received a supply of the pharmaceutical benefit, or of another brand of that benefit, in the period of 4 days immediately preceding the day on which it is supplied to the person; or
  - (b) the supplier of the benefit:
    - (i) reasonably believes that a supply of the pharmaceutical benefit that was previously supplied to the person has been destroyed, lost or stolen; and
    - (ii) writes the words ‘immediate supply necessary’:
      - (A) for a paper-based prescription—on the Medicare Australia/DVA copy; or
      - (B) for an electronic prescription—on the prescription; and
    - (iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires; or
  - (c) the supplier of the benefit:
    - (i) reasonably believes that, having regard to the person’s circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person; and
    - (ii) writes the words ‘immediate supply necessary’:
      - (A) for a paper-based prescription—on the Medicare Australia/DVA copy; or
      - (B) for an electronic prescription—on the prescription; and
    - (iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires.

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*Continued Dispensing*

- (5) Subject to subregulation (2), if the pharmaceutical benefit is supplied to a person by an approved pharmacist (the *supplier*) under subsection 89A(1) of the Act, subregulation (3) or (4) applies as if:
- (a) the person had presented the supplier with a prescription that:
    - (i) had been written by a PBS prescriber in accordance with the Act and these Regulations; and
    - (ii) did not include a medicare number; and
    - (iii) did not direct a repeated supply of the pharmaceutical benefit; and
  - (b) subparagraphs (3)(b)(ii) and (c)(ii) or (4)(b)(ii) and (c)(ii) were omitted, and the words ‘immediate supply necessary’ were required to be written on the repeat authorisation form for the supply; and
  - (c) subparagraphs (3)(b)(iii) and (c)(iii) or (4)(b)(iii) and (c)(iii) were omitted, and the supplier were required to sign the repeat authorisation form mentioned in paragraph (b).

*Medication chart prescriptions*

- (6) Subject to subregulation (2), if the pharmaceutical benefit is supplied by an approved supplier on the basis of a medication chart prescription:
- (a) subregulation (1) does not apply; and
  - (b) subregulation (3) or (4) applies as if the words “immediate supply necessary” and the supplier’s signature were required to be written by the approved supplier on the part of the medication chart, or the part of the copy of that chart, that contains the completed section by which the prescription was written.

**26 Repeat authorisations**

(1AA) This regulation does not apply in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.

(1) Subregulation (1A) applies if:

(a) an approved pharmacist, or an approved medical practitioner, or an approved hospital authority supplies a pharmaceutical benefit under:

(i) a Medicare Australia/DVA copy of a paper-based prescription that contains a direction to supply the benefit more than once; or

(ii) a pharmacist/patient copy of a paper-based prescription to which is attached a deferred supply authorisation that contains a direction to supply the benefit more than once; or

(iii) a pharmacist/patient copy of a paper-based prescription to which is attached a repeat authorisation that contains a direction to supply the benefit more than once; or

(iv) an electronic prescription:

(A) that contains a direction to supply the benefit more than once; or

(B) to which is attached or linked, by electronic means, a deferred supply authorisation that contains a direction to supply the benefit more than once; or

(C) to which is attached or linked, by electronic means, a repeat authorisation that contains a direction to supply the benefit more than once; and

(b) subsequent supplies of the pharmaceutical benefit can be made under the prescription at the time of supply under paragraph (a).

(1A) The approved pharmacist, approved medical practitioner or approved hospital authority must:

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- (a) on or before supplying the pharmaceutical benefit:
  - (i) prepare a repeat authorisation in accordance with a form (including a paper-based or an electronic form) authorised by the Secretary for the supply of the pharmaceutical benefit; and
  - (ii) if the prescription for the benefit is written on an authority prescription—mark the number of the authority prescription on the repeat authorisation; and
  - (iii) if the prescription for the benefit is a paper-based prescription—attach the repeat authorisation to the pharmacist/patient copy and give the repeat authorisation and pharmacist/patient copy to the person to whom the pharmaceutical benefit is supplied; and
  - (iv) if the prescription for the benefit is an electronic prescription—attach or link, by electronic means, the repeat authorisation to the electronic prescription and ensure that the person to whom the pharmaceutical benefit is supplied:
    - (A) is given a print-out of the repeat authorisation and prescription; or
    - (B) is able to access the repeat authorisation and prescription; and
- (b) for the supply of the pharmaceutical benefit on the first occasion—mark on the repeat authorisation:
  - (i) the name and address of the approved supplier; and
  - (ii) the approval number given to the approved supplier under regulation 8A; and
  - (iii) the identifying number given to the prescription by the approved supplier; and
  - (iv) if the pharmaceutical benefit is a substitute benefit for the purposes of subsection 103(2A) of the Act—the brand name of the substitute benefit; and
- (c) for the supply of the pharmaceutical benefit on a subsequent occasion—mark on the repeat authorisation:
  - (i) the date on which the most recent supply was made; and

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- (ii) the identifying number given to the prescription under subparagraph (b)(iii).

Penalty: 0.2 penalty units.

- (1B) An offence against subregulation (1A) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

- (2) An approved pharmacist, approved medical practitioner or approved hospital authority is not authorised to supply a pharmaceutical benefit upon presentation of only the pharmacist/patient copy of a paper-based prescription unless:
  - (a) the approved pharmacist, approved medical practitioner or approved hospital authority is given a repeat authorisation or a deferred supply authorisation that:
    - (i) is related to that pharmacist/patient copy by a number or numbers; and
    - (ii) indicates that the pharmaceutical benefit to be supplied has not been supplied for the number of times directed in the prescription; and
  - (b) there is written on the repeat authorisation or deferred supply authorisation the approval number given to the supplier under regulation 8A; and
  - (c) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written.

**26A Deferred supply authorisations**

- (1A) This regulation does not apply in relation to the supply of a pharmaceutical benefit on the basis of a medication chart prescription.
- (1) Where a prescription contains a direction to supply more than 1 pharmaceutical benefit, the approved pharmacist, approved medical practitioner or approved hospital authority to whom the prescription is presented may, at the request of the person for

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whom the prescription is written, defer the supply of one or more of the pharmaceutical benefits.

- (2) An approved pharmacist, approved medical practitioner or approved hospital authority that defers the supply of a pharmaceutical benefit must:
- (a) prepare a deferred supply authorisation, on and in accordance with a form (including a paper-based or an electronic form) authorised by the Secretary, in respect of each pharmaceutical benefit the deferral of the supply of which is requested; and
  - (b) mark on the deferred supply authorisation prepared by him the number allotted to his or her approval under regulation 8A; and
  - (c) if the prescription is a paper-based prescription:
    - (i) mark on the original and duplicate of the prescription, across the wording relating to the pharmaceutical benefit the supply of which is being deferred, the words 'original supply deferred'; and
    - (ii) attach the deferred supply authorisation prepared by the pharmacist, medical practitioner or hospital authority to the pharmacist/patient copy; and
    - (iii) give the authorisation and pharmacist/patient copy to the person for whom the prescription is written at the same time as the benefit on the original prescription is supplied; and
  - (d) if the prescription is an electronic prescription:
    - (i) mark on the prescription, in relation to the pharmaceutical benefit the supply of which is being deferred, the words 'original supply deferred'; and
    - (ii) attach or link, by electronic means, the deferred supply authorisation prepared by the pharmacist, medical practitioner or hospital authority to the prescription; and
    - (iii) give a print-out of the deferred supply authorisation and prescription to the person to whom the pharmaceutical benefit is supplied or ensure that the deferred supply

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authorisation and prescription are accessible by that person.

- (3) Where an approved hospital authority defers the supply of a pharmaceutical benefit in the circumstance set out in subregulation (1), the authority shall cause the requirements of subregulation (2) to be complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the other pharmaceutical benefit to which the prescription refers is supplied.

**27 Presentation of prescriptions in trading hours**

- (1) An approved pharmacist shall, at all times, keep prominently displayed at each of the premises in respect of which he or she is approved, so as to be readily visible to persons who enter the premises, a notice setting out the normal trading hours during which services for the supply of pharmaceutical benefits are available.
- (2) Subject to regulation 28, a person is entitled to be supplied with a pharmaceutical benefit from an approved pharmacist during normal trading hours only.

**28 Presentation of urgent prescriptions**

- (1) A prescription for the supply of a pharmaceutical benefit marked 'Urgent', that marking being initialled, in the case of a paper-based prescription, by the medical practitioner, participating dental practitioner, authorised midwife or authorised nurse practitioner writing the prescription, may be presented at any time to an approved pharmacist at the premises in respect of which he or she is approved.
- (2) An approved pharmacist must supply a pharmaceutical benefit as soon as practicable if:
- (a) a prescription is presented to the pharmacist under subregulation (1); and
  - (b) any charge lawfully demanded for the prescription is paid.

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Penalty: 0.2 penalty units.

- (3) An offence against subregulation (2) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

- (4) It is a defence to a prosecution for an offence against subregulation (2) if the pharmacist had a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter mentioned in subregulation (4) (see section 13.3 of the *Criminal Code*).

### 30 Special charge for delivery

For subsection 87(4) of the Act, when a pharmaceutical benefit is supplied by delivery at or to a place other than premises in respect of which the approved pharmacist is approved or the premises at which an approved medical practitioner carries on his or her practice, as the case may be, the pharmacist or medical practitioner may make a special charge equal to the cost of delivery.

### 31 Receipt of pharmaceutical benefit

- (1) A person commits an offence if:
- (a) the person receives a pharmaceutical benefit under Part VII of the Act (whether or not for the person's own use) from an approved supplier; and
  - (b) the supply of the pharmaceutical benefit by the approved supplier is not a supply under subsection 89A(1) of the Act; and
  - (c) the pharmaceutical benefit is not supplied by the approved supplier on the basis of a medication chart prescription; and
  - (d) at the time of supply, the approved supplier asks the person to write on the prescription, repeat authorisation or deferred supply authorisation on the basis of which the supply of the pharmaceutical benefit was made:
    - (i) an acknowledgment that the person has received the benefit; and
    - (ii) the date on which the person received the benefit; and

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- (iii) if the benefit is not for the person's own use—the person's address; and
- (e) it is practicable for the person to comply with the request mentioned in paragraph (d); and
- (f) the person does not comply with the request mentioned in paragraph (d).

Penalty: 0.2 penalty units.

- (1A) If a person is required to write an acknowledgment in accordance with subregulation (1) for the supply of a pharmaceutical benefit under an electronic prescription, or an authorisation that relates to an electronic prescription, that requirement is taken to have been met if:
- (a) the acknowledgment is given, in accordance with approved information technology requirements (if any), by means of an approved electronic communication; or
  - (b) the person writes the acknowledgment on a print-out of the electronic prescription or the authorisation that relates to an electronic authorisation.
- (1B) If a person writes an acknowledgment in accordance with paragraph (1A)(b), the approved supplier must write on the electronic prescription, or the authorisation that relates to an electronic prescription, that the person has written the acknowledgment on a print-out of the prescription or authorisation.

Penalty: 0.2 penalty units.

- (2) An approved supplier must not demand an acknowledgment of the supply of a pharmaceutical benefit to a person if the approved supplier has not supplied the benefit to that person.

Penalty: 0.2 penalty units.

- (3) An approved supplier commits an offence if:
- (a) the approved supplier supplies a pharmaceutical benefit under Part VII of the Act, other than under subsection 89A(1) of the Act; and

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- (b) it is not practicable for the approved supplier to obtain, from the person receiving the pharmaceutical benefit (whether or not for the person's own use), a written acknowledgement that the person has received the benefit; and
- (c) the pharmaceutical benefit is not supplied by the approved supplier on the basis of a medication chart prescription; and
- (d) the approved supplier does not certify on the prescription, repeat authorisation or deferred supply authorisation on the basis of which the supply of the pharmaceutical benefit was made:
  - (i) the date on which the pharmaceutical benefit was supplied by the approved supplier; and
  - (ii) the reason why it was not practicable for the approved supplier to obtain the written acknowledgement mentioned in paragraph (b).

Penalty: 0.2 penalty units.

*Continued dispensing supply of pharmaceutical benefit*

- (5) A person commits an offence if:
  - (a) the person receives a pharmaceutical benefit (whether or not for the person's own use) from an approved pharmacist under subsection 89A(1) of the Act; and
  - (b) at the time of the supply, the approved pharmacist asks the person to write on the repeat authorisation form for the supply:
    - (i) an acknowledgement that the person has received the pharmaceutical benefit; and
    - (ii) the date on which the person received the benefit; and
    - (iii) if the benefit is not for the person's own use—the person's address; and
  - (c) it is practicable for the person to comply with the request mentioned in paragraph (b); and
  - (d) the person does not comply with the request mentioned in paragraph (b).

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Penalty: 0.2 penalty units.

- (6) An approved pharmacist commits an offence if:
- (a) the approved pharmacist supplies a pharmaceutical benefit to a person under subsection 89A(1) of the Act; and
  - (b) it is not practicable for the approved pharmacist to obtain, from the person receiving the pharmaceutical benefit (whether or not for the person's own use), a written acknowledgement that the person has received the benefit; and
  - (c) the approved pharmacist does not write on the repeat authorisation form for the supply:
    - (i) the date on which the pharmaceutical benefit was supplied by the approved pharmacist; and
    - (ii) the reason why it was not practicable for the approved pharmacist to obtain the written acknowledgement mentioned in paragraph (b).

Penalty: 0.2 penalty units.

- (7) An offence against this regulation is an offence of strict liability.

## Part 6—Miscellaneous

### 31B Purpose of Part

Unless otherwise specified, this Part is made for section 105 or 140 of the Act.

### 32 Keeping documents—other than for continued dispensing or medication chart prescriptions

- (1) If an approved supplier supplies a pharmaceutical benefit, other than a pharmaceutical benefit that is:
- (a) a dangerous drug; or
  - (b) supplied under subsection 89A(1) of the Act (continued dispensing); or
  - (c) supplied on the basis of a medication chart prescription;
- the approved supplier must keep a document required by subregulation (3A), (3B) or (3C) that relates to the supply for at least 2 years after the supply.

Penalty: 0.2 penalty units.

Note: For a pharmaceutical benefit supplied as mentioned in paragraph (b) or (c), see regulations 32A and 32B.

- (3) An offence against subregulation (1) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

#### *Electronic prescriptions*

- (3A) For subregulation (1), if the supply was on the basis of an electronic prescription, the approved supplier must keep:
- (a) the electronic prescription; and
  - (b) any repeat authorisation or deferred supply authorisation on the basis of which the supply was made.

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*Paper-based prescriptions*

(3B) For subregulation (1), the approved supplier must keep a document referred to in an item in the following table if:

- (a) the supply was on the basis of a paper-based prescription; and
- (b) the supply is of a kind referred to in that item.

Note: If a supply is covered by more than one item in the table, then documents must be kept under each of those items.

**Documents to be kept for paper-based prescriptions**

<b>Item</b>	<b>Kind of supply</b>	<b>Document</b>
1	Both of the following apply in relation to the supply: (a) the supply was the first or only supply of a pharmaceutical benefit authorised by the prescription; (b) a CTS claim is made for the supply.	The Medicare Australia/DVA copy.
2	Both of the following apply in relation to the supply: (a) the supply was on the basis of a repeat authorisation or a deferred supply authorisation; (b) a CTS claim is made for the supply.	The repeat authorisation or deferred supply authorisation.
3	After the supply, there are no remaining supplies of pharmaceutical benefits that are authorised by the prescription.	The pharmacist/patient copy.

*Orders lodged under regulation 16*

(3C) For subregulation (1), if the supply is on the basis of an order lodged under regulation 16, the approved supplier must keep:  
(a) if a CTS claim is made for the supply—the order; and

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- (b) if a claim is made for the supply using the manual system referred to in section 99AAA of the Act—the duplicate of the order.

### *Definition*

- (4) In this regulation:

***dangerous drug*** means a drug or medicinal preparation in respect of which the law of the State or Territory in which the prescription is written provides that a pharmacist who dispenses that drug or medicinal preparation, or who dispenses it on the last of a number of occasions of supply indicated in a prescription for its supply, must take possession of the prescription and cancel it or deliver it to the authority administering that law.

### **32A Keeping documents—continued dispensing**

- (2) An approved pharmacist commits an offence if:
  - (a) the approved pharmacist supplies a pharmaceutical benefit to a person under subsection 89A(1) of the Act; and
  - (b) the approved pharmacist does not keep the following information for at least 2 years from the date on which the pharmaceutical benefit was supplied by the approved pharmacist:
    - (i) the information that supports the claim for payment made under section 99AAA of the Act in relation to the supply of the pharmaceutical benefit, including the repeat authorisation form;
    - (ii) the information, about the supply of the pharmaceutical benefit, that is given to the PBS prescriber who most recently prescribed the pharmaceutical benefit to the person.

Penalty: 0.2 penalty units.

- (3) An offence against this regulation is an offence of strict liability.

**32B Keeping documents—medication chart prescriptions**

- (1) An approved supplier commits an offence if:
  - (a) the approved supplier supplies a pharmaceutical benefit on the basis of a medication chart prescription; and
  - (b) the approved supplier does not keep the medication chart, or the copy of the medication chart, on which the approved supplier wrote the details mentioned in paragraph 21A(2)(d) in relation to the prescription, for at least 2 years from the date of the supply.

Penalty: 0.2 penalty units.

- (3) An offence against this regulation is an offence of strict liability.

**33 Proper stocks to be kept**

- (1) An approved pharmacist must, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits, or to use as ingredients of pharmaceutical benefits.

Penalty: 0.2 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

**35 Standards of composition and purity of pharmaceutical benefits and additives**

- (1) If:
  - (a) under the *Therapeutic Goods Act 1989*, a drug, medicine or substance must be of a particular standard of composition or purity; and
  - (b) the drug, medicine or substance is to be supplied as a pharmaceutical benefit;

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the standard of composition or purity of the drug, medicine or substance is the standard for the purposes of the Act.

(2) If:

- (a) under the *Therapeutic Goods Act 1989*, a drug, medicine or substance must be of a particular standard of composition or purity; and
- (b) the drug, medicine or substance is used as an additive in another drug, medicine or substance (in this subregulation called ‘the finished product’); and
- (c) the finished product is to be supplied as a pharmaceutical benefit;

the standard of composition or purity of the drug, medicine or substance used as an additive is the standard for the purposes of the Act.

Note: See also paragraph 103(5)(f) of the Act.

### 36 Labelling of pharmaceutical benefits—full cost

- (1) A pharmaceutical benefit supplied by an approved supplier must be labelled with the words ‘full cost’ followed by the full cost of the pharmaceutical benefit.
- (2) Subregulation (1) does not apply to:
  - (a) an approved supplier to which section 99AAB of the Act applies; or
  - (b) an approved hospital authority; or
  - (c) a pharmaceutical benefit obtained under subsection 93(2), 93AA(2) or 93AB(2) of the Act; or
  - (d) a pharmaceutical benefit to which subsection 99(2A), (2AB) or (2B) of the Act applies; or
  - (e) the supply of a pharmaceutical benefit on the basis of a medication chart prescription.
- (3) For this regulation, the **full cost** of a pharmaceutical benefit is the sum of:
  - (a) the Commonwealth price of the pharmaceutical benefit; and

- (b) the special patient contribution charged under subsection 87(2A) of the Act.

### **37 Surrender of forms**

- (1) The Secretary may, by notice in writing served on a person, require that person to surrender to the Secretary or to a person specified in the notice, within a time specified in the notice, any forms that have been supplied to that person by or on behalf of the Commonwealth under or for the purpose of Part VII of that Act or these Regulations and that are in the possession of the person.
- (2) A person upon whom a notice is served in pursuance of subregulation (1) shall comply with that notice.

Penalty: 0.2 penalty units.

- (3) An offence against subregulation (2) is an offence of strict liability.

Note: For *strict liability*, see section 6.1 of the *Criminal Code*.

**Part 6A** Price reduction and price disclosure

**Division 1** Price reduction

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**Part 6A—Price reduction and price disclosure**

**Division 1—Price reduction**

**37A Reduction day**

For paragraph 99ADH(2)(b) of the Act, 1 August and 1 December in any year are prescribed.

**Division 2—Price disclosure****Subdivision 1—Interpretation****37C Meaning of *data collection period****Start of first data collection period*

- (1) The first ***data collection period*** for a brand of a pharmaceutical item starts on the brand's start day.

*End of first data collection period*

- (2) If, on the day before the start day for the brand (the ***starting brand***) the price disclosure requirements apply to a related brand of the starting brand, the starting brand's first ***data collection period*** ends when the data collection period for any of the related brands ends.
- (3) Otherwise, the starting brand's first ***data collection period*** ends on:
- (a) if the start day occurs between 2 April and 1 October—the next 31 March; or
  - (b) if the start day occurs between 2 October and 1 April—the next 30 September.

*Start and end of subsequent data collection periods*

- (4) After the first data collection period for a listed brand of a pharmaceutical item, each subsequent ***data collection period*** for the brand:
- (a) starts immediately after the end of the previous data collection period; and
  - (b) ends on the next 31 March or 30 September, whichever is sooner.

Example 1: If a brand to which subregulation (2) applies has a start day of 1 July 2014, and the data collection period for a related brand ends on 30 September 2014:

- (a) the first data collection period starts on 1 July 2014; and

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- (b) the first data collection period ends on 30 September 2014; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2014, 1 April 2015, 1 October 2015 and so on.

Example 2: If a brand to which subregulation (3) applies has a start day of 1 August 2014:

- (a) the first data collection period starts on 1 August 2014; and
- (b) the first data collection period ends on 31 March 2015; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 April 2015, 1 October 2015, 1 April 2016 and so on.

Example 3: If a brand to which subregulation (3) applies has a start day of 1 December 2014:

- (a) the first data collection period starts on 1 December 2014; and
- (b) the first data collection period ends on 30 September 2015; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2015, 1 April 2016, 1 October 2016 and so on.

**37D Meaning of *price sampling day***

A day is a *price sampling day* for a data collection period for a brand of a pharmaceutical item if the day:

- (a) is the first day of a calendar month; and
- (b) the day is within whichever of the following periods commenced earlier:
  - (i) the data collection period;
  - (ii) the data collection period for another brand of the same pharmaceutical item.

**37E Special rules for certain listed brands**

- (1) Subregulations (3), (4) and (5) apply to a listed brand of a pharmaceutical item if:
  - (a) paragraphs 99ADB(3B)(a) and (b) of the Act apply to the listed brand; and
  - (b) a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

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- (2) Subregulations (4) and (5) apply to a listed brand of a pharmaceutical item if:
- (a) the start day for the listed brand is the relevant day; and
  - (b) a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

*Approved ex-manufacturer price on relevant day*

- (3) For paragraph 99ADB(3B)(c) of the Act, the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the relevant day is the approved ex-manufacturer price of the brand on the start day minus any amount that would have been added, and plus any amount that would have been deducted, because of a price adjustment, had the brand been a listed brand in the period:
- (a) starting on the relevant day; and
  - (b) ending immediately before the brand's start day.

*Deemed data collection period and approved ex-manufacturer price for determining weighted average disclosed price*

- (4) For the purpose of determining the weighted average disclosed price of the listed brand under Subdivision 2, the brand is taken to have had a data collection period:
- (a) beginning on the earliest day on which the data collection period began for any related brand of the listed brand; and
  - (b) ending on the day before the relevant day.
- (5) For the purpose of determining the weighted average disclosed price of the listed brand under Subdivision 2, the approved ex-manufacturer price of the listed brand on a price sampling day is taken to have been the approved ex-manufacturer price of the listed brand on the brand's start day minus any amount that would have been added, and plus any amount that would have been deducted, because of a price adjustment, had the brand been a listed brand in the period:
- (a) starting on the price sampling day; and

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(b) ending immediately before the brand's start day.

Note: This enables an average approved ex-manufacturer price to be worked out for the purpose of determining the weighted average disclosed price.

**Subdivision 2—Weighted average disclosed price**

**37F Method for determining weighted average disclosed price of listed brand of pharmaceutical item**

- (1) This Subdivision is made for subsection 99ADB(6) of the Act.
- (2) Regulations 37G to 37S prescribe the method for determining the weighted average disclosed price of a listed brand of a pharmaceutical item in respect of a data collection period for the listed brand.
- (3) When using the method, the Minister may disregard information provided under regulation 37T for a data collection period if the information is incomplete.

Note: Section 99ADA of the Act provides that Division 3B (Price disclosure) of Part VII of the Act does not apply to brands of exempt items.

**37G Step 1—Net revenue for brand**

- (1) Work out the net revenue for the listed brand of the pharmaceutical item for the data collection period for the brand.
- (2) The *net revenue* is the revenue from sales of the listed brand for the data collection period, other than for the listed brand's initial month, minus the value of any incentive given in relation to sales of the listed brand for the data collection period, other than for the listed brand's initial month.

**37H Step 2—Adjusted volume for brand**

- (1) Work out the adjusted volume of the listed brand of the pharmaceutical item sold for the data collection period for the brand.
- (2) The *adjusted volume* is the number of packs of the listed brand sold for the data collection period, other than for the listed brand's initial month, worked out as if the size of the pack equals the pricing quantity of the listed brand on the final day.

Note: For the definition of *pricing quantity*, see subsection 84AK(1) of the Act.

**37J Step 3—Average approved ex-manufacturer price for brand**

- (1) Work out the average approved ex-manufacturer price of the listed brand of the pharmaceutical item for the data collection period for the brand.
- (2) The *average approved ex-manufacturer price* is the amount worked out by:
  - (a) adding together, for each price sampling day for the listed brand for the data collection period:
    - (i) if the listed brand had an approved ex-manufacturer price on the price sampling day—the approved ex-manufacturer price; or
    - (ii) if the listed brand did not have an approved ex-manufacturer price on the price sampling day—the approved ex-manufacturer price of a listed brand of the same pharmaceutical item; and
  - (b) dividing that amount by the number of price sampling days for the listed brand for the data collection period.

Note: A price sampling day may be within the data collection period for another brand of the same pharmaceutical item (see regulation 37D).

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*Adjustment for variation in pricing quantity*

- (3) If the pricing quantity of a brand on a price sampling day is different from the pricing quantity of the brand on the final day, for the purposes of subregulation (2) the approved ex-manufacturer price of the brand on the price sampling day is taken to be:

$$\frac{AEMP}{PQ1} \times PQ2$$

where:

**AEMP** means the approved ex-manufacturer price of the brand on the price sampling day (for the pricing quantity of the brand on the price sampling day).

**PQ1** means the pricing quantity of the brand on the price sampling day.

**PQ2** means the pricing quantity of the brand on the final day.

**37K Step 4—Disclosed price for brand**

- (1) Work out the disclosed price of the listed brand of the pharmaceutical item for the data collection period for the brand.
- (2) The **disclosed price** is:
- (a) if the adjusted volume (see step 2) of the listed brand is zero or less—zero; or
  - (b) if the adjusted volume (see step 2) of the listed brand is more than zero:
    - (i) the amount worked out by dividing the net revenue for the listed brand (see step 1) by the adjusted volume; or
    - (ii) if the amount worked out under subparagraph (i) is more than the average approved ex-manufacturer price for the listed brand for the data collection period—the average approved ex-manufacturer price of the listed brand.

**37L Step 5—Price percentage difference of brand**

- (1) Work out the price percentage difference of the listed brand of the pharmaceutical item for the data collection period.
- (2) The *price percentage difference* of the listed brand is the amount (expressed as a percentage to 2 decimal places) worked out as follows:
  - (a) subtract the listed brand's disclosed price for the data collection period (see step 4) from the listed brand's average approved ex-manufacturer price for the data collection period (see step 3); and
  - (b) divide that amount by the listed brand's average approved ex-manufacturer price for the data collection period.

**37M Step 6—Repeat steps for each brand of pharmaceutical item**

- (1) For each other brand of the same pharmaceutical item (including delisted brands) work out the price percentage difference of the brand for the data collection period ending on the same day as the data collection period of the listed brand.
- (2) The price percentage difference of the other brand is worked out using steps 1 to 5, reading references to the listed brand as references to the other brand.
- (3) If the other brand of the pharmaceutical item is a delisted brand on the final day, then the pricing quantity of the delisted brand on the final day is taken to be:
  - (a) if there is a listed brand of the same pharmaceutical item on the final day—the pricing quantity of the listed brand; or
  - (b) if there is no listed brand of the same pharmaceutical item on the final day—the pricing quantity of the last listed brand immediately before it was delisted.

Note: The pricing quantity of the brand on the final day is needed for working out the adjusted volume (step 2) and the average approved ex-manufacture price (step 3).

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**37N Step 7—Total adjusted volume of brands of pharmaceutical item**

- (1) Work out the total adjusted volume of the brands of the pharmaceutical item.
- (2) The *total adjusted volume* is the amount worked out by adding together the adjusted volume for each brand of the pharmaceutical item for the brand's data collection period.

**37P Step 8—Weighted average percentage difference of brands of pharmaceutical item**

- (1) Work out the weighted average percentage difference of the brands of the pharmaceutical item.
- (2) The *weighted average percentage difference* is:
  - (a) if the total adjusted volume of the brands of the pharmaceutical item (see step 7) is zero or less—zero; or
  - (b) if the total adjusted volume of the brands of the pharmaceutical item (see step 7) is more than zero—the amount (expressed as a percentage to 2 decimal places) worked out by:
    - (i) for each brand of the pharmaceutical item, multiplying the adjusted volume of the brand for the brand's data collection period (see step 2) by the price percentage difference of the brand for the data collection period (see step 5); and
    - (ii) adding up each of those amounts; and
    - (iii) dividing that amount by the total adjusted volume of the brands of the pharmaceutical item.

**37Q Step 9—Repeat steps for each pharmaceutical item with related brands**

- (1) For each brand (including delisted brands) of a pharmaceutical item with the same drug and manner of administration as the listed brand but a different form (the *other pharmaceutical item*), other

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than an exempt item, work out the price percentage difference of the brand for the data collection period ending on the same day as the data collection period of the listed brand.

- (2) The price percentage of difference of a brand of the other pharmaceutical item is worked out using steps 1 to 5, reading references to the listed brand as references to the brand of the other pharmaceutical item.
- (3) If a brand of the other pharmaceutical item is a delisted brand on the final day, then the pricing quantity of the delisted brand on the final day is taken to be:
  - (a) if there is a listed brand of the other pharmaceutical item on the final day—the pricing quantity of the listed brand of the other pharmaceutical item; or
  - (b) if there is no listed brand of the other pharmaceutical item on the final day—the pricing quantity of the last listed brand of the other pharmaceutical item immediately before it was delisted.

Note: The pricing quantity of the brand on the final day is needed for working out the adjusted volume (step 2) and the average approved ex-manufacture price (step 3).

- (4) For each pharmaceutical item with the same drug and manner of administration as the listed brand but a different form, other than an exempt item, work out the weighted average percentage difference of the brands of the pharmaceutical item (using steps 7 and 8).

### **37R Step 10—Weighted average percentage difference for listed brand and all related brands**

- (1) Work out the weighted average percentage difference for the listed brand and all related brands.
- (2) The *weighted average percentage difference* is the amount (expressed as a percentage to 2 decimal places) worked out as follows:

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- (a) for each pharmaceutical item with the same drug and manner of administration as the listed brand (including the pharmaceutical item of the listed brand):
    - (i) multiply the total adjusted volume for the brands of the pharmaceutical item (see step 7) by the average approved ex-manufacturer price for a brand of the pharmaceutical item (see step 3); and
    - (ii) multiply that amount by the weighted average percentage difference of the brands of the pharmaceutical item (see step 8);
  - (b) add up the amounts worked out under subparagraph (a)(ii);
  - (c) add up the amounts worked out under subparagraph (a)(i);
  - (d) divide the amount worked out under paragraph (b) by the amount worked out under paragraph (c).
- (3) However:
- (a) if the amount worked out under paragraph (2)(c) is zero or less, the *weighted average percentage difference* is zero; and
  - (b) if the amount worked out under paragraph (2)(d) is 99% or more, the *weighted average percentage difference* is 99%.

**37S Step 11—Weighted average disclosed price for listed brand of pharmaceutical item**

- (1) Work out the weighted average disclosed price of the listed brand of the pharmaceutical item for the data collection period.
- (2) The *weighted average disclosed price* of the listed brand of the pharmaceutical item is the average approved ex-manufacturer price for the listed brand reduced by the weighted average percentage difference for all related brands (see step 10).
- (3) However, if the pricing quantity of the listed brand of the pharmaceutical item on the final day is different from the pricing quantity of the listed brand on the relevant day, the *weighted average disclosed price* is:

$$\frac{WR}{PQ1} \times PQ2$$

where:

**PQ1** means the pricing quantity of the listed brand on the final day.

**PQ2** means the pricing quantity of the listed brand on the relevant day.

**WR** means the average approved ex-manufacturer price for the listed brand reduced by the weighted average percentage difference for all related brands (see step 10).

Note: See section 99ADHA of the Act for price reductions for brands listed after the end of the data collection period.

### **Subdivision 3—Price disclosure requirements**

#### **37T Price disclosure requirements**

- (1) This regulation is made for subsection 99ADC(1) of the Act.

*Prescribed information*

- (2) The responsible person must provide the following information in relation to the supply of a brand of a pharmaceutical item, other than the supply to a public hospital:
- (a) the start and end dates of the period to which the information relates;
  - (b) the name of the brand;
  - (c) the name of the responsible person;
  - (d) the name of the drug in the pharmaceutical item;
  - (e) the form of the drug, including its strength;
  - (f) the manner of administration of the form of the drug;
  - (g) the number or quantity of units in a pack (the number of tablets in a pack, for example);
  - (h) the number of packs sold;

**Part 6A** Price reduction and price disclosure

**Division 2** Price disclosure

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- (i) the revenue from sales of the brand, excluding GST;
- (j) if any incentive is given in relation to the brand:
  - (i) the kind of incentive; and
  - (ii) the value of the incentive, excluding GST.
- (3) If information is provided under paragraph (2)(i), the information must not also be provided under paragraph (2)(j).
- (4) The information mentioned in each of paragraphs (2)(h), (i) and (j), to the extent that the information relates to the brand's initial month, must be provided separately.
- (5) An amount provided under paragraph (2)(i) or (j) must be:
  - (a) expressed in Australian dollars; and
  - (b) rounded to the nearest whole dollar, rounding 50 cents upwards.

*Prescribed person*

- (6) The responsible person must provide the information to:
  - (a) Australian Healthcare Associates Pty Ltd (ABN 82 072 790 848); or
  - (b) if the responsible person receives written notice from the Department to provide the information to the Secretary—the Secretary.

*Prescribed manner and form*

- (7) The responsible person must provide the information in a form approved by the Secretary.
- (8) The completed form must:
  - (a) include all the statements and information required by the form; and
  - (b) be signed (or authorised for electronic transmission) by a person who is authorised by the responsible person to provide the information.

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*Prescribed times*

- (9) Subject to subregulation (10), the responsible person must provide the information:
- (a) for each period between 1 April and 30 September in a year—before the end of 11 November in that year; and
  - (b) for each period between 1 October and the next 31 March—before the end of the next 12 May.
- (10) However, for the period between a brand's start day and the next 31 March or 30 September, whichever is the sooner, the responsible person must provide the information:
- (a) if the start day happens between 1 April and 30 September in a year—before the end of 11 November in that year; or
  - (b) if the start day happens between 1 October and the next 31 March—before the end of the next 12 May.

## Part 7—Arrangements of the Pharmaceutical Benefits Advisory Committee

### 38 Definitions for Part

In this Part:

**Chairperson** means the Chairperson appointed under regulation 39.

**Committee** means the Pharmaceutical Benefits Advisory Committee established under section 100A of the Act.

**Drug Utilisation Sub-Committee** means the sub-committee of that name established under section 101A of the Act.

**Economics Sub-Committee** means the sub-committee of that name established under section 101A of the Act.

**member** means a member of the Committee.

### 38A Appointments to Committee—nominating bodies

- (1) For paragraph 100B(1A)(a) of the Act, the following consumer organisations are prescribed:
  - (a) the Consumers' Health Forum of Australia;
  - (b) the Australian Federation of AIDS Organisations;
  - (c) the Australian Consumers' Association.
- (2) For paragraph 100B(1A)(b) of the Act, the following professional associations of health economists are prescribed:
  - (a) the Australian Health Economics Society Inc;
  - (b) the Economic Society of Australia Inc.
- (3) For paragraph 100B(1A)(c) of the Act, the following professional associations of pharmacists are prescribed:
  - (a) the Pharmacy Guild of Australia;

- (b) the Pharmaceutical Society of Australia;
  - (c) the Society of Hospital Pharmacists of Australia.
- (4) For paragraph 100B(1A)(d) of the Act, the following professional associations of medical practitioners are prescribed:
- (a) the Australian Medical Association Limited;
  - (b) the Royal Australian College of General Practitioners;
  - (c) the Australian Divisions of General Practice Limited;
  - (d) the Doctors Reform Society—Australia Inc;
  - (e) the Australian Federation of Medical Women Inc.
- (5) For paragraph 100B(1A)(e) of the Act, the following professional associations of clinical pharmacologists are prescribed:
- (a) the Royal Australasian College of Physicians;
  - (b) the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.
- (6) For paragraph 100B(1A)(f) of the Act, the following professional associations of specialists are prescribed:
- (a) the Australian Medical Association Limited;
  - (b) the Royal Australasian College of Physicians;
  - (c) the Committee of Presidents of Medical Colleges.

### **38B Number of nominations for appointment**

For subsection 100B(1B) of the Act, each body prescribed for subsection 100B(1A) of the Act must be asked to nominate at least 3 persons for selection for appointment as members of the Committee.

### **39 Chairperson**

The Minister must appoint one of the members of the Committee as the Chairperson of the Committee.

## Regulation 40

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### 40 Resignation

- (1) The Chairperson of the Committee may resign as Chairperson by notice in writing given to the Minister.
- (2) A member of the Committee may resign from the Committee by notice in writing given to the Minister.

### 41 Presiding member

- (1) The Chairperson must preside at any meeting of the Committee at which he or she is present or, under subregulation 42(3), is taken to be present.
- (2) If the Chairperson is absent from a meeting, the members attending the meeting must elect a member to preside at that meeting.

### 42 Meetings of the Committee

- (1) The Chairperson may, at any time, by notice in writing to all members, convene a meeting of the Committee at the time and place set out in the notice.
- (2) For the purposes of subregulation (1), the Chairperson and members of the Committee may:
  - (a) attend a meeting in person; or
  - (b) participate in a meeting by telephone or closed circuit television.
- (3) If the Chairperson, or a member, participates in a meeting in accordance with paragraph 2(b), he or she is taken to be present at the meeting.
- (4) The Committee must keep minutes of its meetings.

### 43 Quorum

At a meeting of the Committee, a quorum is the number of members who constitute a majority of the membership of the Committee.

**44 Voting**

- (1) At a meeting of the Committee, the Chairperson and other members present each have a deliberative vote.
- (2) A matter requiring a decision at a meeting must be determined by a majority of the votes of the Chairperson and other members present and voting.
- (3) If an equal number of votes is cast for and against a matter at a meeting:
  - (a) the Chairperson, or the member elected under subregulation 41(2) to preside at the meeting, may exercise a casting vote; and
  - (b) if the Chairperson or that member declines to exercise a casting vote—the matter is resolved in the negative.
- (4) Decisions of the Committee must be recorded in the minutes of the meeting.

**45 Disclosure of pecuniary interests by Chairperson and members**

- (1) The Chairperson must tell the Minister in writing, as soon as practicable after the beginning of each financial year, of all direct or indirect pecuniary interests that the Chairperson has, or proposes to acquire, in a business or in a body corporate carrying on a business that could conflict with that person's duties as Chairperson.
- (2) Each member must tell the Minister in writing, as soon as practicable after the beginning of each financial year, of all direct or indirect pecuniary interests that the member has, or proposes to acquire, in a business or in a body corporate carrying on a business that could conflict with that person's duties as a member.
- (3) If the Chairperson or a member does not have an interest of the kind mentioned in subregulation (1) or (2) respectively, he or she must give a statement to that effect to the Minister.

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- (4) If the Chairperson, or the presiding member, has a direct or indirect pecuniary interest in a matter that is to be considered at a meeting, the Chairperson or the presiding member:
  - (a) must disclose the interest to the members present at the meeting; and
  - (b) must not take part in the meeting during the consideration of that matter unless the members present at the meeting agree that the Chairperson or the presiding member may take part in the meeting.
- (5) If the Chairperson, or the presiding member, is precluded from taking part in a meeting or part of a meeting because of the operation of paragraph (4)(b), the members present must elect one of the members present to act in the place of the Chairperson or the presiding member for the duration of the Committee's consideration of the matter.
- (6) If a member (other than the Chairperson or the presiding member) has a direct or indirect pecuniary interest in a matter that is to be considered at a meeting, the member:
  - (a) must disclose the interest to the Chairperson, or the presiding member, at the commencement of the meeting; and
  - (b) must not take part in the meeting during the consideration of that matter unless the Chairperson, or the presiding member, allows the member to take part in the meeting.
- (7) The following matters must be recorded in the minutes of a meeting:
  - (a) a disclosure made under subregulation (4) or (6);
  - (b) an agreement under paragraph (4)(b);
  - (c) the consent of the Chairperson, or the presiding member, under paragraph (6)(b).
- (8) In this regulation, *presiding member* means, in relation to a meeting of the Committee, a member elected under subregulation 41(2) to preside at the meeting.

**46 Resolutions without a formal meeting**

If a majority of the members of the Committee sign a document that includes a statement that they are in favour of a resolution in the terms set out in the document, the resolution is taken to have been passed at a meeting of the Committee:

- (a) on the day on which the document is signed; or
- (b) if the members sign the document on different days—on the day on which the document is signed by the member who completes the majority.

**47 Reports and recommendations**

- (1) A report or a recommendation made to the Minister by the Committee as part of its consideration of a matter must be in writing.
  - (2) If:
    - (a) the members are not unanimous in agreeing to a report or a recommendation; and
    - (b) a member who is not part of the majority asks the Chairperson to include, as part of the report or recommendation:
      - (i) a statement that the members are not unanimous; or
      - (ii) an explanation of the opinion of the member; or
      - (iii) a separate report or recommendation made by the member;
- the report or recommendation must include the matter requested by the member.

**48 Remuneration for chair and members of sub-committees***Fees and allowances payable to chairs*

- (1) For paragraph 140(a) of the Act, the fees and allowances payable to the Chair of the Drug Utilisation Sub-Committee and the Chair of the Economics Sub-Committee are the amounts payable to the

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Chairperson (within the meaning of section 118 of the Act) of the Pharmaceutical Services Federal Committee of Inquiry in accordance with a determination made by the Remuneration Tribunal, as in force from time to time.

*Fees and allowances payable to other members*

- (2) For paragraph 140(a) of the Act, the fees and allowances payable to a member (other than the Chair) of the Drug Utilisation Sub-Committee or the Economics Sub-Committee are the amounts payable to a member (other than the Chairperson) of the Pharmaceutical Services Federal Committee of Inquiry in accordance with a determination made by the Remuneration Tribunal, as in force from time to time.

## **Part 8—Transitional provisions**

**Part 8** Transitional provisions

**Division 3** Provisions for National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014

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**Division 3—Provisions for National Health  
(Pharmaceutical Benefits) Amendment (Price  
Disclosure) Regulation 2014**

**54 Application of Regulations**

- (1) These Regulations, as amended by the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*, apply in relation to a data collection period that ends after 1 February 2014.
- (2) This regulation applies subject to regulation 55.

**55 Data collection periods**

- (1) The data collection period for a brand that, under the old Regulations:
  - (a) started on a date, or between the dates, mentioned in column 1 of the following table (the *brand's start date*); and
  - (b) was due to end on the date mentioned in column 2 of the table;  
instead ends on the date mentioned in column 3 of the table.

<b>New data collection period end dates</b>			
<b>Item</b>	<b>Column 1 Starts on or between</b>	<b>Column 2 Due to end on</b>	<b>Column 3 Instead ends on</b>
1	1 February 2013	30 September 2014	31 March 2014
2	2 February 2013 to 1 June 2013	31 May 2014	31 March 2014
3	1 June 2013	30 September 2014	31 March 2014
4	2 June 2013 to 1 October 2013	30 September 2014	31 March 2014
5	1 October 2013	30 September 2014	31 March 2014
6	2 October 2013 to	31 January 2015	30 September 2014

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<b>New data collection period end dates</b>			
<b>Item</b>	<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
	<b>Starts on or between</b>	<b>Due to end on</b>	<b>Instead ends on</b>
	1 February 2014		
7	1 February 2014	30 September 2015	30 September 2014
8	2 February 2014 to 1 April 2014	31 May 2015	30 September 2014
9	2 April 2014 to 1 June 2014	31 May 2015	31 March 2015

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- (2) If the brand is a listed brand, the next data collection period for the brand starts on the day after the date mentioned in column 3 of the table.
- (3) The responsible person for a brand to which item 6, 7 or 8 of the table applies must provide the information required under regulation 37H of the old Regulations for the period between the brand's start date and 31 March 2014, in accordance with regulations 37HA to 37J of the old Regulations, before the end of 12 May 2014.
- (4) In this regulation:

**brand** means a listed or delisted brand of a pharmaceutical item, other than an exempt item.

**old Regulations** means these Regulations as in force immediately before these Regulations were amended by the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*.

## 56 Expiry of this Division

This Division expires on 3 April 2016 as if it had been repealed by another regulation.

**Division 4—Provisions for National Health  
(Pharmaceutical Benefits) Amendment  
(Medication Chart Prescriptions)  
Regulation 2015**

**57 Application of amendments—general**

Except as set out in this Division, the amendments made by Part 1 of Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015* apply in relation to a prescription written on or after 1 April 2015.

**58 Savings provision—medication chart prescriptions for persons receiving treatment in or at a residential care service**

- (1) A PBS prescriber may write a medication chart prescription during the period of 2 years starting on 1 April 2015 in accordance with regulations 19 and 19AA as in force immediately before that date.

Note: Before 1 April 2015, a medication chart prescription could only be written to prescribe a pharmaceutical benefit for a person receiving treatment in or at a residential care service.

- (2) For subregulation (1), a reference in regulation 19AA (as in force immediately before 1 April 2015) to a condition determined under paragraph 93A(2)(b) of the Act is a reference to any condition determined under that paragraph that applies under the *National Health (Residential Medication Chart) (Repeal) Determination 2015* for the purposes of this regulation.

- (3) These Regulations (other than regulation 31), as in force immediately before 1 April 2015, continue to apply in relation to a medication chart prescription written under subregulation (1).

Note: For the application of regulation 31 in relation to a medication chart prescription written under subregulation (1), see subregulations 60(3) and (4).

**59 Transitional provision—medication chart prescriptions for persons receiving treatment in or at a hospital**

- (1) Subregulation (2) applies in relation to the writing of a prescription for a pharmaceutical benefit under regulation 19AA, as in force on or after 1 April 2015, if:
- (a) the person for whom the pharmaceutical benefit is to be prescribed is receiving treatment in or at an approved hospital; and
  - (b) a declaration made by the Minister under subregulation (3) of this regulation is in force at the time the prescription is written; and
  - (c) either of the following apply:
    - (i) the prescription is written before 1 July 2016;
    - (ii) the prescription would be an electronic prescription and is written on or after 1 July 2016 and before 1 April 2017.
- (2) The hospital must be a listed approved hospital under the declaration.
- (3) The Minister may, by legislative instrument, declare that an approved hospital is a **listed approved hospital** for the purposes of this regulation.

Note 1: For variation and revocation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

Note 2: See also subsection 13(3) of the *Legislative Instruments Act 2003* (rule-maker may identify matter by referring to a class or classes of matters).

**60 Application of amendments to document retention provisions**

- (1) Regulation 18A, as amended by Part 1 of Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015*, applies in relation to a pharmaceutical benefit obtained by an approved medical practitioner on or after 1 April 2015.

**Part 8** Transitional provisions

**Division 4** Provisions for National Health (Pharmaceutical Benefits) Amendment  
(Medication Chart Prescriptions) Regulation 2015

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- (2) However, if:
- (a) an approved medical practitioner obtains a pharmaceutical benefit for the purpose of supplying the pharmaceutical benefit under section 93 of the Act; and
  - (b) information relating to the pharmaceutical benefit is given in accordance with the old Claims Rules, as those Rules continue to apply under rule 12 of the new Claims Rules; then regulation 18A, as in force immediately before 1 April 2015, applies in relation to the obtaining of the pharmaceutical benefit.
- (3) Regulations 31, 32 and 32A, as amended by Part 1 of Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015*, apply in relation to the supply of a pharmaceutical benefit on or after 1 April 2015.
- (4) However, if information relating to the supply is given in accordance with the old Claims Rules as those Rules continue to apply under rule 12 of the new Claims Rules, then regulations 31, 32 and 32A, as in force immediately before 1 April 2015, apply in relation to the supply of the pharmaceutical benefit.
- (5) In this Regulation:
- new Claims Rules* means the *National Health (Claims and under co-payment data) Rules 2012*, as in force on 1 April 2015.
- old Claims Rules* means the *National Health (Claims and under co-payment data) Rules 2012*, as in force immediately before 1 April 2015.

**61 Repeal of this Division**

This Division is repealed on 1 April 2019.

## **Schedule 6—Prescribed offices for subsections 84DA(5) and 84E(5) of the Act**

(regulations 9AF and 9BA)

1. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826  
SYDNEY NSW 2000
  2. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826  
MELBOURNE VIC 3000
  3. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services
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**Schedule 6** Prescribed offices for subsections 84DA(5) and 84E(5) of the Act

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GPO Box 9826  
BRISBANE QLD 4000

4. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826  
PERTH WA 6000

5. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826  
ADELAIDE SA 5000

6. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826

HOBART TAS 7000

7. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826  
CANBERRA ACT 2600
  
8. Pharmaceutical Benefits Scheme  
Claims Section  
Department of Human Services  
GPO Box 9826  
DARWIN NT 0800

## Endnotes

Endnote 1—About the endnotes

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## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Endnotes about misdescribed amendments and other matters are included in a compilation only as necessary.

### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the amendment is set out in the endnotes.

**Endnote 2—Abbreviation key**

A = Act	orig = original
ad = added or inserted	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
am = amended	pres = present
amdt = amendment	prev = previous
c = clause(s)	(prev...) = previously
C[x] = Compilation No. x	Pt = Part(s)
Ch = Chapter(s)	r = regulation(s)/rule(s)
def = definition(s)	Reg = Regulation/Regulations
Dict = Dictionary	reloc = relocated
disallowed = disallowed by Parliament	renum = renumbered
Div = Division(s)	rep = repealed
exp = expires/expired or ceases/ceased to have effect	rs = repealed and substituted
F = Federal Register of Legislative Instruments	s = section(s)/subsection(s)
gaz = gazette	Sch = Schedule(s)
LI = Legislative Instrument	Sdiv = Subdivision(s)
LIA = <i>Legislative Instruments Act 2003</i>	SLI = Select Legislative Instrument
(md) = misdescribed amendment	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
o = order(s)	<u>underlining</u> = whole or part not commenced or to be commenced
Ord = Ordinance	

## Endnotes

### Endnote 3—Legislation history

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### Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
1960 No. 17	29 Feb 1960	1 Mar 1960	
1960 No. 90	28 Oct 1960	1 Nov 1960	—
1960 No. 102	19 Dec 1960	r. 1: 1 Feb 1961 r. 2: 1 Jan 1961	—
1961 No. 59	28 Apr 1961	1 May 1961	—
1961 No. 137	27 Oct 1961	1 Nov 1961	—
1962 No. 34	18 Apr 1962	1 May 1962	—
1962 No. 101	31 Oct 1962	1 Nov 1962	—
1962 No. 114	24 Dec 1962	1 Jan 1963	—
1963 No. 34	26 Apr 1963	1 May 1963	—
1963 No. 69	12 Aug 1963	12 Aug 1963	—
1963 No. 107	31 Oct 1963	1 Nov 1963	—
1964 No. 12	30 Jan 1964	1 Feb 1964	—
1964 No. 57	30 Apr 1964	1 May 1964	—
1964 No. 135	30 Oct 1964	1 Nov 1964	—
1965 No. 51	30 Apr 1965	1 May 1965	—
1965 No. 151	28 Oct 1965	1 Nov 1965	—
1965 No. 152	28 Oct 1965	1 Nov 1965	—
1966 No. 80	28 Apr 1966	1 May 1966	—
1966 No. 144	27 Oct 1966	1 Nov 1966	—
1967 No. 67	1 June 1967	1 June 1967	—
1967 No. 116	31 Aug 1967	1 Sept 1967	—
1967 No. 158	30 Nov 1967	1 Dec 1967	—
1968 No. 44	28 Mar 1968	1 Apr 1968	—
1968 No. 76	11 July 1968	11 July 1968	—
1968 No. 88	1 Aug 1968	1 Aug 1968	—
1968 No. 146	29 Nov 1968	1 Dec 1968	—

## Endnote 3—Legislation history

<b>Number and year</b>	<b>FRLI registration or gazettal</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
1969 No. 44	27 Mar 1969	1 Apr 1969	—
1969 No. 107	31 July 1969	1 Aug 1969	—
1969 No. 185	28 Nov 1969	1 Dec 1969	—
1970 No. 39	25 Mar 1970	1 Apr 1970	—
1970 No. 94	30 July 1970	1 Aug 1970	—
1970 No. 119	4 Sept 1970	7 Sept 1970	—
1970 No. 186	27 Nov 1970	1 Dec 1970	—
1971 No. 44	1 Apr 1971	1 Apr 1971	—
1971 No. 101	30 July 1971	1 Aug 1971	—
1971 No. 136	25 Oct 1971	1 Nov 1971	—
1971 No. 154	26 Nov 1971	1 Dec 1971	—
1972 No. 32	16 Mar 1972	1 Apr 1972	—
1972 No. 121	28 July 1972	1 Aug 1972	—
1972 No. 205	30 Nov 1972	1 Dec 1972	—
1973 No. 15	1 Feb 1973	1 Feb 1973	—
1973 No. 57	22 Mar 1973	1 Apr 1973	—
1973 No. 139	26 July 1973	1 Aug 1973	—
1973 No. 229	29 Nov 1973	1 Dec 1973	—
1974 No. 37	29 Mar 1974	1 Apr 1974	—
1974 No. 126	30 July 1974	1 Aug 1974	—
1974 No. 222	27 Nov 1974	1 Dec 1974	—
1975 No. 50	1 Apr 1975	1 Apr 1975	—
1975 No. 148	31 July 1975	1 Aug 1975	—
1975 No. 209	21 Nov 1975	1 Dec 1975	—
1976 No. 84	24 Mar 1976	r. 3: 1 Apr 1976 Remainder: 24 Mar 1976	—
1976 No. 150	26 July 1976	1 Aug 1976	—
1976 No. 195	14 Sept 1976	14 Sept 1976	—
1976 No. 255	1 Dec 1976	1 Dec 1976	—

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## Endnotes

### Endnote 3—Legislation history

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<b>Number and year</b>	<b>FRLI registration or gazettal</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
1977 No. 39	28 Mar 1977	1 Apr 1977	—
1977 No. 125	29 July 1977	1 Aug 1977	—
1977 No. 221	24 Nov 1977	1 Dec 1977	—
1978 No. 47	29 Mar 1978	1 Apr 1978	—
1978 No. 142	27 July 1978	1 Aug 1978	—
1978 No. 153	24 Aug 1978	24 Aug 1978	—
1978 No. 245	30 Nov 1978	1 Dec 1978	—
1979 No. 51	30 Mar 1979	1 Apr 1979	—
1979 No. 55	2 Apr 1979	2 Apr 1979	—
1979 No. 144	31 July 1979	1 Aug 1979	—
1979 No. 250	30 Nov 1979	1 Dec 1979	—
1980 No. 69	31 Mar 1980	1 Apr 1980	—
1980 No. 213	29 July 1980	1 Aug 1980	—
1980 No. 338	28 Nov 1980	1 Dec 1980	—
1981 No. 52	31 Mar 1981	1 Apr 1981	—
1981 No. 212	31 July 1981	1 Aug 1981	—
1981 No. 218	14 Aug 1981	14 Aug 1981	—
1981 No. 345	30 Nov 1981	1 Dec 1981	—
1982 No. 69	19 Mar 1982	19 Mar 1982	—
1982 No. 76	31 Mar 1982	1 Apr 1982	—
1982 No. 179	30 July 1982	1 Aug 1982	—
1982 No. 334	30 Nov 1982	1 Dec 1982	—
1982 No. 372	31 Dec 1982	1 Jan 1983	—
1983 No. 28	31 Mar 1983	1 Apr 1983	—
1983 No. 102	15 July 1983	15 July 1983	—
1983 No. 116	29 July 1983	1 Aug 1983	—
1983 No. 292	30 Nov 1983	1 Dec 1983	—
1984 No. 50	30 Mar 1984	1 Apr 1984	—
1984 No. 148	11 July 1984	11 July 1984	—

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## Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
1984 No. 169	31 July 1984	1 Aug 1984	—
1984 No. 342	30 Nov 1984	1 Dec 1984	—
1985 No. 32	1 Apr 1985	1 Apr 1985	—
1985 No. 184	1 Aug 1985	1 Aug 1985	—
1985 No. 320	29 Nov 1985	1 Dec 1985	—
1986 No. 38	27 Mar 1986	1 Apr 1986	—
1986 No. 194	31 July 1986	1 Aug 1986	—
1986 No. 319	31 Oct 1986	31 Oct 1986	—
1986 No. 320	31 Oct 1986	1 Nov 1986	—
1986 No. 391	22 Dec 1986	22 Dec 1986	—
1987 No. 47	31 Mar 1987	1 Apr 1987	—
1987 No. 262	12 Nov 1987	12 Nov 1987	—
1987 No. 279	30 Nov 1987	1 Dec 1987	—
1988 No. 56	29 Apr 1988	1 May 1988	—
1989 No. 330	30 Nov 1989	r 1, 2, 8: 1 Dec 1989 Remainder: 1 Jan 1990 (r 1) Note: disallowed by the Senate on 22 Dec 1989	—
1990 No. 226	12 July 1990	1 Aug 1990	—
1990 No. 267	21 Aug 1990	1 Aug 1990	—
1990 No. 337	31 Oct 1990	1 Nov 1990	—
1990 No. 338	31 Oct 1990	1 Nov 1990 ( <i>see</i> r. 1)	—
1990 No. 437	21 Dec 1990	21 Dec 1990	—
1991 No. 1	22 Jan 1991	22 Jan 1991	—
1991 No. 474	23 Dec 1991	1 Jan 1992	—
1992 No. 226	10 July 1992	10 July 1992	—
1994 No. 348	18 Oct 1994	rr. 7–9: 1 Jan 1995 r. 21.2: 1 Dec 1994 Remainder: 1 Nov 1994	—
1996 No. 70	31 May 1996	1 June 1996	—

## Endnotes

### Endnote 3—Legislation history

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<b>Number and year</b>	<b>FRLI registration or gazettal</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
1998 No. 374	22 Dec 1998	1 Jan 1999	—
2000 No. 369	20 Dec 2000	1 Jan 2001 (r. 2)	—
2001 No. 68	12 Apr 2001	12 Apr 2001	—
2002 No. 9	21 Feb 2002	21 Feb 2002	—
2002 No. 239	11 Oct 2002	1 Feb 2003	—
2002 No. 344	20 Dec 2002	rr. 1–3 and Schedule 1: 20 Dec 2002 Remainder: 1 Aug 2003	—
2003 No. 193	31 July 2003	1 Aug 2003	—
2004 No. 389	23 Dec 2004	13 Jan 2005 (r. 2)	—
2005 No. 207	19 Sept 2005 (F2005L02673)	1 Oct 2005 (r. 2)	—
2006 No. 121	2 June 2006 (F2006L01614)	1 July 2006	—
2006 No. 200	28 July 2006 (F2006L02405)	1 Mar 2007	—
2007 No. 160	25 June 2007 (2007L01518)	1 July 2007	—
2007 No. 225	24 July 2007 (F2007L02206)	1 Aug 2007	—
2008 No. 54	14 Apr 2008 (F2008L00583)	15 Apr 2008	—
2008 No. 116	20 June 2008 (F2008L01021)	21 June 2008	—
2009 No. 195	30 July 2009 (F2009L02523)	31 July 2009	—
2010 No. 49	25 Mar 2010 (F2010L00568)	26 Mar 2010	—
2010 No. 115	7 June 2010 (F2010L01069)	8 June 2010	—

## Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
2010 No. 231	21 July 2010 (F2010L01979)	rr. 1–3 and Schedule 1: 22 July 2010 Schedule 2: 1 Nov 2010	—
2010 No. 295	25 Nov 2010 (F2010L02950)	26 Nov 2010	—
2010 No. 296	26 Nov 2010 (F2010L02953)	1 Dec 2010	rr. 4–7, 9 and 10 r. 8 (am. by 2012 No. 56, Sch. 1 [item 1])
<b>as amended by</b>			
2012 No. 56	20 Apr 2012 (F2012L00902)	21 Apr 2012	—
2010 No. 327	9 Dec 2010 (F2010L03077)	10 Dec 2010	—
2011 No. 29	16 Mar 2011 F2011L00427)	17 Mar 2011	—
2011 No. 120	30 June 2011 (F2011L01364)	1 July 2011	—
2012 No. 55	20 Apr 2012 (F2012L00901)	21 Apr 2012	—
2012 No. 141	29 June 2012 (F2012L01443)	1 July 2012	—
2012 No. 168	13 July 2012 (F2012L01552)	1 Oct 2012	—
2012 No. 299	11 Dec 2012 (F2012L02388)	12 Dec 2012	—
53, 2013	12 Apr 2013 (F2013L00650)	13 Apr 2013	—
60, 2014	2 June 2014 (F2014L00636)	3 June 2014	—
23, 2015	17 Mar 2015 (F2015L00310)	1 Apr 2015	Sch 1 (item 102)

**Endnotes**

Endnote 3—Legislation history

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## Endnote 4—Amendment history

## Endnote 4—Amendment history

Provision affected	How affected
<b>Part 1</b>	
Heading to Part I.....	rep. 2006 No. 200
Heading to Part 1.....	ad. 2006 No. 200
<b>Division 1.1</b>	
Heading to Div. 1.1.....	ad. 2006 No. 200
r. 1.....	rs. 1998 No. 374
r. 2.....	am. 1977 No. 39
r. 3.....	rep No 195, 1976
r. 4.....	am No 39, 1977
Renumbered r. 3.....	No 374, 1998
	rep No 23, 2015
r. 4.....	ad No 374, 1998
	rep No 23, 2015
r. 5.....	am. 1960 No. 90; 1976 No. 195; 1977 No. 39; 1979 Nos. 55 and 250; 1981 No. 218; 1982 No. 372; 1983 No. 102; 1986 Nos. 319 and 391; 1988 No. 56; 1990 No. 437; 1991 Nos. 1 and 474; 1992 No. 226; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2002 Nos. 239 and 344; 2004 No. 389; 2005 No. 207; 2006 No. 200; 2007 No. 225; 2008 No. 54; 2010 Nos. 231 and 296; 2012 Nos. 141 and 168; No 60, 2014; No 23, 2015
<b>Division 1.2</b>	
Div. 1.2 of Part 1.....	ad. 2006 No. 200
r. 5A.....	ad No 200, 2006; No 23, 2015
r. 5B.....	ad. 2006 No. 200
	am. 2008 No. 54
r. 5C.....	ad. 2006 No. 200
r. 5D.....	ad No 200, 2006; No 23, 2015
r. 5E.....	ad No 200, 2006; No 23, 2015
r. 5F.....	ad No 200, 2006; No 23, 2015
r. 6.....	am. 1977 No. 39; 1991 No. 474

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
	rep. 1994 No. 348
r. 7 .....	am. 1977 No. 39
	rep. 1984 No. 148
<b>Part 2</b>	
Heading to Part II .....	am. 1979 No. 55; 1982 No. 69; 1986 No. 91
	rs. 2008 No. 54;
	rep. 2012 No. 141
Heading to Part 2 .....	ad. 2012 No. 141
Heading to r. 8 .....	rs. 2001 No. 68
r. 8 .....	am. 1977 No. 39
	rs. 1981 No. 218
	am. 1982 No. 69; 1986 No. 391; 1988 No. 56; 1994 No. 348; 1996 No. 70;
	2001 No. 68
r. 8AA .....	ad. 2008 No. 54
	rs. 2010 No. 231
r. 8A .....	ad. 1979 No. 55
	rs. 1981 No. 218
	am. 1982 No. 69; 1986 No. 391; 1988 No. 56; 2004 No. 389; 2006
	No. 121; 2008 No. 54; 2010 No. 231
r. 9 .....	am. 1967 No. 158; 1977 No. 39; 1986 No. 391; 1994 No. 348
	rs. 2002 No. 9
Heading to Part IIAAA .....	rep. 2012 No. 141
Heading to Part 2A .....	ad. 2012 No. 141
	rep No 23, 2015
Part 2A .....	rep No 23, 2015
r. 9AAA .....	ad. 2007 No. 225
	rep. 2010 No. 296
r. 9AAB .....	ad. 2007 No. 225
	rep. 2010 No. 296
r 9AAC .....	ad No 225, 2007
	rep No 23, 2015

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
r. 9AAD.....	ad. 2007 No. 225 rep. 2010 No. 49
<b>Part 2B</b>	
Heading to Part IIAA.....	rep. 2012 No. 141
Heading to Part 2B .....	ad. 2012 No. 141
Part IIAA.....	ad. 1991 No. 1
r. 9AA.....	ad. 1991 No. 1 am. 1991 No. 474; 1992 No. 226; 1994 No. 348; 2002 No. 344
r. 9AB.....	ad. 1991 No. 1 am. 1992 No. 226; 1994 No. 348; 2002 No. 344
r. 9AC.....	ad. 1991 No. 1 am. 1992 No. 226; 1994 No. 348; 2002 No. 344
r. 9AD.....	ad. 1991 No. 1 am. 1992 No. 226
r. 9AE.....	ad. 1991 No. 1
Heading to r. 9AF.....	rs. 2002 No. 344
r. 9AF .....	ad. 1991 No. 1 am. 1994 No. 348; 2002 No. 344 rs. 2012 No. 141
<b>Part 2C</b>	
Heading to Part IIA .....	rep. 2012 No. 141
Heading to Part 2C .....	ad. 2012 No. 141
Part IIA.....	ad. 1986 No. 319
r 9A .....	ad No 319, 1986 am No 330, 1989 (disallowed) am No 226, 1990; No 267, 1990; No 338, 1990; No 474, 1991; No 226, 1992; No 344, 2002
r 9B.....	ad No 319, 1986 am No 330, 1989 (disallowed) rs No 437, 1990 am No 474, 1991; No 226, 1992; No 344, 2002

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<b>Provision affected</b>	<b>How affected</b>
r. 9BA.....	ad. 1987 No. 262 am. 1994 No. 348; 2002 No. 344 rs. 2012 No. 141
r 9C.....	ad No 319, 1986 am No 330, 1989 (disallowed) am No 226, 1990 rs No 437, 1990 am No 226, 1992; No 344, 2002
r 9D .....	ad No 319, 1986 am No 330, 1989 (disallowed) am No 226, 1990 rs No 437, 1990 am No 226, 1992; No 344, 2002
r 9E.....	ad No 319, 1986 am No 330, 1989 (disallowed) am No 226, 1990 rs No 437, 1990 am No 226, 1992
r. 9F .....	ad. 1986 No. 319
<b>Part 3</b>	
Heading to Part III.....	am. 1979 No. 250 rep. 2012 No. 141
Heading to Part 3 .....	ad. 2012 No. 141
r. 10 .....	am. 1967 No. 158; 1977 No. 39 rep. 1987 No. 47
rr. 11, 12 .....	am. 1977 No. 39 rep. 1987 No. 47
r 13 .....	am No 152, 1965; No 39, 1977; No 5, 1977 rs No 56, 1988 am No 70, 1996; ; No 193, 2003; No 200, 2006; No 54, 2008; No 231, 2010; No 23, 2015

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
Note to r. 13(1) .....	ad. 2012 No. 141
r. 14 .....	am. 1965 No. 152; 1968 No. 44; 1977 No. 39; 1979 Nos. 55 and 250; 1980 No. 338; 1981 No. 52 rep. 1987 No. 47
<b>Part 4</b>	
Heading to Part IV .....	rs. 1979 No. 250; 2010 No. 231 rep. 2012 No. 141
Heading to Part 4 .....	ad. 2012 No. 141
r. 14 .....	ad. 2010 No. 231
r. 15 .....	rs. 1963 No. 69 am. 1994 No. 348; 2004 No. 389 rs. 2010 No. 231; 2012 No. 168
Heading to r. 16 .....	rs. 2012 No. 168
r. 16 .....	am. 1963 No. 69; 1977 No. 39; 1986 No. 391; 1988 No. 56; 1994 No. 348; 2002 No. 344; 2006 No. 200 rs. 2010 No. 231 am. 2012 No. 168
Heading to r. 17 .....	rs. 2012 No. 168
r. 17 .....	am. 1967 No. 158; 1977 No. 39; 1986 No. 391 rs. 2002 No. 9 am. 2006 No. 200 rs. 2010 No. 231
Heading to r. 18 .....	rs. 2012 No. 168
r. 18 .....	am No 69, 1963; No 39, 1977; No 391, 1986; No 200, 2006 rs No 231, 2010 am No 168, 2012 rs No 23, 2015
r. 18A .....	ad No 69, 1963 am No 158, 1967; No 39, 1977; No 391, 1986; No 56, 1988; No 348, 1994 rs No 9, 2002 am No 23, 2015

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
<b>Part 5</b>	
Heading to Part V .....	rep. 2012 No. 141
Heading to Part 5 .....	ad. 2012 No. 141
r. 18B.....	ad. 2012 No. 141
r 18C.....	ad No 23, 2015
r 19 .....	rs No 90, 1960  am 1965 No. 152; 1971 No. 136; 1974 No. 126; 1977 No. 39; 1978 No. 153; 1979 No. 55; 1982 No. 372; 1986 No. 391; 1987 Nos. 47 and 279; 1988 No. 56; 1991 No. 474; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2002 Nos. 239 and 344; 2004 No. 389; 2005 No. 207; 2006 No. 200; 2007; No 54, 2008; No. 160; 2008; 2010; No. 231; 2011 No. 120; No 141, 2012; No 168, 2012; No 23, 2015; No 23, 2015
r 19AA.....	ad No 141, 2015  rs No 23, 2015
Heading to r. 19A .....	rs. 2001 No. 68; 2012 No. 141
r. 19A .....	ad. 1971 No. 136  rep. 1976 No. 84  ad. 1983 No. 102  am. 1986 Nos. 319 and 391; 1990 No. 437; 1991 No. 1; 2001 No. 68; 2002 No. 344; 2004 No. 389; 2006 No. 200; 2012 No. 141
r. 19B.....	ad. 1988 No. 56  am. 1991 No. 474  rs. 2002 No. 9
r. 20 .....	am. 1977 No. 39; 1979 No. 55; 1981 No. 218; 1987 No. 47; 1994 No. 348  rep. 2012 No. 141
r 21 .....	am. 1960 No. 90; 1965 No. 152; 1977 No. 39; 1978 No. 153; 1979 No. 55; 1981 No. 52; 1985 No. 320; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56; 1998 No. 374  rs. 1994 No. 348  am No 200, 2006; No 141, 2012; No 23, 2015
r 21A .....	ad No 141, 2012  am No 23, 2015

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<b>Provision affected</b>	<b>How affected</b>
r 21B.....	ad No 141, 2012 am No 23, 2015
r 21C.....	ad No 141, 2012 No 23, 2015
r 22 .....	am No 158, 1967; No 39, 1977; No 55, 1979; No 391, 1986; No 47, 1987; No 56, 1988; No 348, 1994; No 9, 2002; No 207, 2005; No 200, 2006; No 54, 2008; No 120, 2011; No 141, 2012; No 23, 2015
r. 23 .....	am. 1960 No. 90 rs. 1965 No. 152 am. 1977 No. 39; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56 rep. 1994 No. 348
r. 24 .....	am. 1977 No. 39; 1979 No. 55; 1986 No. 319; 2004 No. 389; 2010 No. 231; 2012 No. 141
r. 24A .....	ad. 2012 No. 141
r 25 .....	am No 330, 1989 (disallowed) am No 337, 1990; No 348, 1994; No 374, 1998; No 68, 2001; No 207, 2005; No 200, 2006; No 141, 2012; No 23, 2015
r 26 .....	am 1965 No. 152; 1968 No. 76; 1977 No. 39; 1978 No. 153; 1979 No. 55; 1981 Nos. 52 and 218; 1982 No. 372; 1983 No. 102; 1985 No. 320; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56; 1990 No. 437; 1991 Nos. 1 and 474; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2001 No. 68; 2002 No. 9; 2005 No. 207; 2006 No. 200; 2012 No. 141; No 23, 2015
r 26AA.....	ad No 141, 2012 rep No 23, 2015
r 26A .....	ad No 153, 1978 am No 55, 1979; No 218, 1981; No 372, 1982; No 102, 1983; No 319, 1986; No 391, 1986; No 56, 1988; No 437, 1990; No 1, 1991; No 474, 1991; No 348, 1994; No 70, 1996; No 374, 1998; No 68, 2001; No 389, 2004; No 200, 2006; No 141, 2012; No 23, 2015
r. 27 .....	am. 1977 No. 39; 1986 No. 391; 1988 No. 56; 1994 No. 348; 2004 No. 389
r. 28 .....	am. 1967 No. 158; 1977 No. 39; 1979 No. 55; 1986 No. 391; 2002 No. 9; 2004 No. 389; 2006 No. 200; 2010 No. 231
r. 29 .....	am. 1967 No. 158

## Endnotes

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<b>Provision affected</b>	<b>How affected</b>
	rs. 1976 No. 195
	rep. 1986 No. 319
r. 30 .....	am. 1986 No. 391; 1994 No. 348; 2004 No. 389; 2012 No. 141
r 31 .....	am No 90, 1960; No 152, 1965; No 158, 1967; No 39, 1977; No 102, 1983; No 319, 1986; No 391, 1986; No 47, 1987; No 56, 1988; No 437, 1990; No 1, 1991
	rs No 348, 1994
	am No 9, 2002; No 200, 2006; No 141, 2012; No 23, 2015
<b>Part 6</b>	
Heading to Part VI.....	rep. 2012 No. 141
Heading to Part 6.....	ad. 2012 No 141
r. 31B.....	ad. 2012 No. 141
r 32 .....	am No 152, 1965; No 158, 1967; No 39, 1977; No 153, 1978; No 391, 1986; No 348, 1994; No 70, 1996; No 374, 1998
	rs No 9, 2002
	am No 344, 2002; No 200, 2006; No 141, 2012; No 23, 2015
r 32A .....	ad No 141, 2012
	am No 23, 2015
r 32B.....	ad No 141, 2012
	am No 23, 2015
r. 33 .....	am. 1967 No. 158; 1977 No. 39; 1986 No. 391
	rs. 2002 No. 9
r. 34 .....	am. 1977 No. 39; 1979 No. 55; 1986 No. 391; 1988 No. 56
	rep. 1994 No. 348
r. 35 .....	am. 1962 No. 34; 1964 Nos. 57 and 135; 1969 No. 107; 1977 No. 39; 1987 No. 47
	rs. 1994 No. 348
Note to r. 35.....	ad. 2012 No. 141
r 36 .....	am No 39, 1977; No 338, 1994
	rep No 70, 1996
	ad No 344, 2002
	am No 231, 2010; No 141, 2012; No 168, 2012; No 23, 2015

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
r. 37 .....	am. 1967 No. 158; 1977 No. 39; 1988 No. 56; 2002 No. 9
r 37AA.....	ad No 141, 2012 rep No 23, 2015
<b>Pt 6A</b>	
Heading to Part VIA .....	rep. 2012 No. 141
Heading to Pt 6A .....	ad. 2012 No. 141 rs. No. 53, 2013; No 60, 2014
<b>Div 1</b>	
Heading to Div. 1 .....	ad. 2010 No. 296
of Part VIA .....	rep. 2012 No. 141
Heading to Div. 1 .....	ad. 2012 No. 141
of Part 6A .....	rs No 60, 2014
Heading to r. 37A .....	rs. 2012 No. 141; No 60, 2014
r. 37A .....	ad. 2007 No. 225 am. 2010 No. 296; 2012 No. 168; No. 53, 2013 rs No 60, 2014
hdg to Div 1A of Pt 6A.....	ad. No. 53, 2013 rep No 60, 2014
r 37B.....	ad No 225, 2007 rep No 23, 2015
<b>Div 2</b>	
Div 2 of Pt 6A .....	ad No 60, 2014
<b>Sdiv 1</b>	
hdg to Sdiv 1 of Div 2 .....	ad No 60, 2014
r. 37C.....	ad. 2007 No. 225 rep. 2012 No. 168 ad No 60, 2014
Heading to r. 37D .....	rs. 2010 No. 296 rep. 2012 No. 168 ad No 60, 2014
r. 37D .....	ad. 2007 No. 225

## Endnotes

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<b>Provision affected</b>	<b>How affected</b>
	am. 2008 No. 116; 2010 No. 296
	rep. 2012 No. 168
	ad No 60, 2014
r. 37DA.....	ad. 2010 No. 296
	rep. 2012 No. 168
Heading to Div. 2 ..... of Part VIA	ad. 2010 No. 296
	rep. 2012 No. 141
Heading to Div. 2 ..... of Part 6A	ad. 2012 No. 141
	rep No 60, 2014
r. 37DB.....	ad. 2010 No. 296
	rep No 60, 2014
r. 37E.....	ad. 2007 No. 225
	am. 2010 No. 296; No. 53, 2013
	rs No 60, 2014
Note to r. 37E(4).....	rs. 2010 No. 296
	rep No 53, 2013
r. 37EA.....	ad. 2010 No. 296
	am. 2012 No. 141
	rep No 60, 2014
r. 37EB.....	ad. 2010 No. 296
	am. No. 53, 2013
	rep No 60, 2014
Note 1 to r. 37EB(2).....	rs. No. 53, 2013
	rep No 60, 2014
Note 2 to r. 37EB(2).....	rs. No. 53, 2013
	rep No 60, 2014
r. 37EC.....	ad. 2010 No. 296
	am. No. 53, 2013
	rep No 60, 2014
Heading to r. 37ED.....	am. 2012 No. 168
	rep No 60, 2014

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<b>Provision affected</b>	<b>How affected</b>
r. 37ED .....	ad. 2010 No. 296 am. 2012 No. 168 rep No 60, 2014
Note to r. 37ED(6) .....	rep. 2012 No. 168
r. 37EE .....	ad. 2010 No. 296 am. 2012 No. 168 rep No 60, 2014
r. 37EF .....	ad. 2010 No. 296 am. No. 53, 2013 rep No 60, 2014
r. 37EG .....	ad. 2010 No. 296 am. No. 53, 2013 rep No 60, 2014
r. 37EH .....	ad. 2010 No. 296 am. No. 53, 2013 rep No 60, 2014
<b>Sdiv 2</b>	
hdg to Sdiv 2 of Div 2 .....	ad No 60, 2014
hdg to r 37F .....	rs No. 53, 2013; No 60, 2014
r. 37F .....	ad. 2007 No. 225 am. 2008 No. 116 rs. 2010 No. 296; 2012 No. 168 am. No. 53, 2013 rs No 60, 2014
r. 37FA .....	ad. 2012 No. 168 am. No. 53, 2013 rep No 60, 2014
Note 1 to r. 37FA(1) .....	rep. No. 53, 2013
Note 2 to r. 37FA(1) .....	rep. No. 53, 2013
r. 37G .....	ad. 2007 No. 225 rs. 2010 No. 296

## Endnotes

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<b>Provision affected</b>	<b>How affected</b>
	am. 2012 No. 168; No. 53, 2013 rs No 60, 2014
Note to r. 37G(5) .....	ad, No. 53, 2013 rep No 60, 2014
Heading to Div. 3 .....	ad. 2010 No. 296
of Part VIA	rep. 2012 No. 141
Heading to Div. 3 .....	ad. 2012 No. 141
of Part 6A	rep No 60, 2014
r. 37H .....	ad. 2007 No. 225 rs. 2010 No. 296 am. 2012 No. 168; No. 53, 2013 rs No 60, 2014
Note 1 to r. 37H(1)	
Renumbered Note .....	No. 53, 2013 rep No 60, 2014
Note 2 to r. 37H(1) .....	rep. No. 53, 2013
r. 37HA.....	ad. 2008 No. 116 rs. 2011 No. 29 am. 2012 No. 55 rep No 60, 2014
Note to r. 37HA(2) .....	ad. No. 53, 2013 rep No 60, 2014
r. 37I.....	ad. 2007 No. 225 am. 2010 No. 296 rep No 60, 2014
Note to r. 37I(2).....	ad. No. 53, 2013 rep No 60, 2014
r. 37J.....	ad. 2007 No. 225 rs. 2010 No. 296 am. 2012 No. 168; No. 53, 2013 rs No 60, 2014

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<b>Provision affected</b>	<b>How affected</b>
Note to r. 37J(6).....	rep. No. 53, 2013
r. 37JA.....	ad. 2010 No. 296; No. 53, 2013 rep No 60, 2014
Note to r. 37JA(6).....	rep. No. 53, 2013
Heading to Div. 4 ..... of Part VIA	ad. 2010 No. 296 rep. 2012 No. 141
Heading to Div. 4 ..... of Part 6A	ad. 2012 No. 141 rep No 60, 2014
r. 37K.....	ad. 2009 No. 195 am. 2010 No. 296 rs No 60, 2014
r 37L.....	ad No 60, 2014
r 37M.....	ad No 60, 2014
r 37N.....	ad No 60, 2014
r 37P.....	ad No 60, 2014
r 37Q.....	ad No 60, 2014
r 37R.....	ad No 60, 2014
r 37S.....	ad No 60, 2014
<b>Sdiv 3</b>	
Sdiv 3 of Div 2.....	ad No 60, 2014
r 37T.....	ad No 60, 2014
<b>Part 7</b>	
Part 7.....	ad. 1994 No. 348
Heading to r. 38.....	rs. 2012 No. 141
r. 38.....	ad. 1994 No. 348 am. 2000 No. 369; 2009 No. 195
Heading to r. 38A.....	rs. 2012 No. 141
r. 38A.....	ad. 2000 No. 369 am. 2001 No. 68
Heading to r. 38B.....	rs. 2012 No. 141
r. 38B.....	ad. 2000 No. 369

## Endnotes

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<b>Provision affected</b>	<b>How affected</b>
r. 39 .....	ad. 1994 No. 348
r. 40 .....	ad. 1994 No. 348 rs. 2000 No. 369
r. 41 .....	ad. 1994 No. 348
r. 42 .....	ad. 1994 No. 348
r. 43 .....	ad. 1994 No. 348
r. 44 .....	ad. 1994 No. 348 am. 1996 No. 70
r. 45 .....	ad. 1994 No. 348 am. 1996 No. 70
r. 46 .....	ad. 1994 No. 348
r. 47 .....	ad. 1994 No. 348
r 48 .....	ad No 348, 1994 rep No 369, 2000 ad No 195, 2009 am No 115, 2010; No 327, 2010 rs No 299, 2012; No 23, 2015
<b>Pt 8</b>	
Pt 8 .....	ad. 2012 No. 168
Div 1 of Pt 8 .....	rep No 60, 2014
r. 49 .....	ad. 2012 No. 168 rep No 60, 2014
r. 50 .....	ad. 2012 No. 168 rep No 60, 2014
Div 2 of Pt 8 .....	ad No 53, 2013 rep No 23, 2015
r. 51 .....	ad. No. 53, 2103 rep No 60, 2014
r. 52 .....	ad No. 53, 2103 rep No 60, 2014
r 53 .....	ad No 53, 2103

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## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
	rep No 23, 2015
<b>Division 3</b>	
Division 3 .....	ad No 60, 2014 rep <u>3 Apr 2016 (r 56)</u>
r 54 .....	ad No 60, 2014 rep <u>3 Apr 2016 (r 56)</u>
r 55 .....	ad No 60, 2014 rep <u>3 Apr 2016 (r 56)</u>
r 56 .....	ad No 60, 2014 rep <u>3 Apr 2016 (r 56)</u>
<b>Division 4</b>	
Division 4 .....	ad No 23, 2015 rep <u>1 Apr 2019 (r 61)</u>
r 57 .....	ad No 23, 2015 rep <u>1 Apr 2019 (r 61)</u>
r 58 .....	ad No 23, 2015 rep <u>1 Apr 2019 (r 61)</u>
r 59 .....	ad No 23, 2015 rep <u>1 Apr 2019 (r 61)</u>
r 60 .....	ad No 23, 2015 rep <u>1 Apr 2019 (r 61)</u>
r 61 .....	ad No 23, 2015 rep <u>1 Apr 2019 (r 61)</u>
Schedule 1 .....	ad. 2007 No. 225 rep. 2010 No. 296
Schedule 2 .....	ad. 2007 No. 225 rep. 2010 No. 296
Schedule 3 .....	ad No 225, 2007 rep No 23, 2015
Schedule 4 .....	ad. 2007 No. 225 rep. 2010 No. 49

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<b>Provision affected</b>	<b>How affected</b>
Schedule 5 .....	ad No 225, 2007 rs No 116, 2008 am No 49, 2010; No 295, 2010 rep No 23, 2015
<b>Schedule 6</b>	
Schedule 1 .....	ad. 2002 No. 344 am. 2005 No. 207
Renumbered Schedule 6.....	2007 No. 225
Schedule 6 .....	rs. 2011 No. 120
Schedule 7 .....	ad. 2012 No. 168 rep No 60, 2014
Schedule 8 .....	ad. No. 53, 2013 rep No 60, 2014
Schedule 9 .....	ad No 53, 2013 rep No 23, 2015
Heading to Schedule.....	ad. 1994 No. 348 rep. 2002 No. 344
Heading to The Schedules .....	rep. 1977 No. 39
Heading to First Schedule.....	rep. 1977 No. 39
Heading to Schedule 1 .....	ad. 1977 No. 39 rep. 1987 No. 47
First Schedule.....	rs. 1960 No. 90 am. 1961 No. 59 rs. 1961 No. 137; 1962 Nos. 34 and 101 am. 1963 No. 34 rs. 1963 No. 107 am. 1964 No. 12 rs. 1964 Nos. 57 and 135; 1965 No. 51 am. 1965 No. 151 rs. 1966 No. 80 am. 1966 No. 144

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
	rs. 1967 No. 67
	am. 1967 No. 116
	rs. 1967 No. 158
	am. 1968 Nos. 44, 88 and 146; 1969 No. 44
	rs. 1969 No. 107
	am. 1969 No. 185; 1970 Nos. 39, 94 and 186
	rs. 1971 Nos. 44 and 101
	am. 1971 No. 154
	rs. 1972 No. 32
	am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57
	rs. 1973 No. 139
	am. 1973 No. 229; 1974 No. 37
	rs. 1974 No. 126
	am. 1974 No. 222; 1975 No. 50
	rs. 1975 No. 148
	am. 1975 No. 209
	rs. 1976 No. 84
	am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 1 .....	rs. 1977 No. 125
	am. 1977 No. 221; 1978 Nos. 47 and 142
	rs. 1978 No. 245
	am. 1979 No. 51
	rs. 1979 No. 144
	am. 1979 No. 250; 1980 Nos. 69 and 213
	rs. 1980 No. 338
	am. 1981 No. 52
	rs. 1981 No. 212
	am. 1981 No. 345; 1982 No. 76
	rs. 1982 No. 179
	am. 1982 No. 334; 1983 No. 28
	rs. 1983 No. 116

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
	am. 1983 No. 292; 1984 Nos. 50, 169 and 342
	rs. 1985 Nos. 32 and 184
	am. 1985 No. 320; 1986 No. 38
	rs. 1986 No. 194
	am. 1986 No. 320
	rep. 1987 No. 47
Heading to Second Schedule.....	rep. 1977 No. 39
Heading to Schedule 2.....	ad. 1977 No. 39
	rep. 1987 No. 47
Second Schedule.....	rs. 1960 No. 90; 1961 Nos. 59 and 137; 1962 Nos. 34 and 101
	am. 1962 No. 114; 1963 No. 34
	rs. 1963 No. 107; 1964 Nos. 57 and 135; 1965 No. 51
	am. 1965 No. 151
	rs. 1966 Nos. 80 and 144; 1967 No. 67
	am. 1967 No. 116
	rs. 1967 No. 158
	am. 1968 Nos. 44, 88 and 146; 1969 No. 44
	rs. 1969 Nos. 107 and 185
	am. 1970 Nos. 39, 94 and 186
	rs. 1971 Nos. 44 and 101
	am. 1971 No. 154
	rs. 1972 No. 32
	am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57
	rs. 1973 No. 139
	am. 1973 No. 229; 1974 No. 37
	rs. 1974 No. 126
	am. 1974 No. 222; 1975 No. 50
	rs. 1975 No. 148
	am. 1975 No. 209
	rs. 1976 No. 84

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
	am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 2 .....	am. 1977 No. 39
	rs. 1977 No. 125
	am. 1977 No. 221; 1978 Nos. 47 and 142
	rs. 1978 No. 245
	am. 1979 No. 51
	rs. 1979 No. 144
	am. 1979 No. 250; 1980 Nos. 69 and 213
	rs. 1980 No. 338
	am. 1981 No. 52
	rs. 1981 No. 212
	am. 1981 No. 345; 1982 No. 76
	rs. 1982 No. 179
	am. 1982 No. 334; 1983 No. 28
	rs. 1983 No. 116
	am. 1983 No. 292; 1984 Nos. 50, 169 and 342
	rs. 1985 Nos. 32 and 184
	am. 1985 No. 320; 1986 No. 38
	rs. 1986 No. 194
	am. 1986 No. 320
	rep. 1987 No. 47
Heading to Third Schedule .....	rep. 1977 No. 39
Heading to Schedule 3 .....	ad. 1977 No. 39
	rep. 1987 No. 47
Third Schedule .....	rs. 1960 No. 90
	am. 1960 No. 102
	rs. 1961 Nos. 59 and 137; 1962 Nos. 34 and 101
	am. 1962 No. 114; 1963 No. 34
	rs. 1963 No. 107
	am. 1964 No. 12

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
	rs. 1964 Nos. 57 and 135; 1965 Nos. 51 and 151; 1966 Nos. 80 and 144; 1967 No. 67
	am. 1967 No. 116
	rs. 1967 No. 158
	am. 1968 Nos. 44, 88 and 146; 1969 No. 44
	rs. 1969 No. 107
	am. 1969 No. 185; 1970 Nos. 39, 94 and 186
	rs. 1971 Nos. 44 and 101
	am. 1971 No. 154
	rs. 1972 No. 32
	am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57
	rs. 1973 No. 139
	am. 1973 No. 229; 1974 No. 37
	rs. 1974 No. 126
	am. 1974 No. 222; 1975 No. 50
	rs. 1975 No. 148
	am. 1975 No. 209
	rs. 1976 No. 84
	am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 3 .....	rs. 1977 No. 125
	am. 1977 No. 221; 1978 Nos. 47 and 142
	rs. 1978 No. 245
	am. 1979 No. 51
	rs. 1979 No. 144
	am. 1979 No. 250; 1980 Nos. 69 and 213
	rs. 1980 No. 338
	am. 1981 No. 52
	rs. 1981 No. 212
	am. 1981 No. 345; 1982 No. 76
	rs. 1982 No. 179
	am. 1982 No. 334; 1983 No. 28

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
	rs. 1983 No. 116
	am. 1983 No. 292; 1984 Nos. 50, 169 and 342
	rs. 1985 Nos. 32 and 184
	am. 1985 No. 320; 1986 No. 38
	rs. 1986 No. 194
	am. 1986 No. 320
	rep. 1987 No. 47
Heading to Fourth Schedule.....	rep. 1977 No. 39
Heading to Schedule 4.....	ad. 1977 No. 39 rep. 1987 No. 47
Fourth Schedule.....	rs. 1961 No. 137; 1962 Nos. 34 and 101; 1963 No. 107; 1964 Nos. 57 and 135; 1965 No. 51; 1966 No. 80 am. 1966 No. 144 rs. 1967 Nos. 67, 116 and 158; 1969 No. 107 am. 1969 No. 185; 1970 Nos. 39 and 186 rs. 1971 Nos. 44 and 101; 1972 No. 32 am. 1973 No. 57 rs. 1973 No. 139 am. 1973 No. 229 rs. 1974 No. 126 am. 1974 No. 222; 1975 No. 50 rs. 1975 No. 148; 1976 No. 84
Schedule 4.....	rs. 1977 No. 125 am. 1978 No. 142 rs. 1978 No. 245 am. 1979 No. 51 rs. 1979 No. 144; 1980 No. 338 am. 1981 No. 52 rs. 1981 No. 212; 1982 No. 179; 1983 No. 116 am. 1983 No. 292

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
	rs. 1985 Nos. 32 and 184; 1986 No. 194
	am. 1986 No. 320
	rep. 1987 No. 47
Heading to Fifth Schedule .....	rep. 1977 No. 39
Heading to Schedule 5 .....	ad. 1977 No. 39
	rep. 1987 No. 47
Fifth Schedule .....	rs. 1960 No. 90
	am. 1960 No. 102
	rs. 1961 Nos. 59 and 137; 1962 Nos. 34 and 101
	am. 1962 No. 114; 1963 No. 34
	rs. 1963 No. 107
	am. 1964 No. 12
	rs. 1964 Nos. 57 and 135; 1965 Nos. 51 and 151; 1966 Nos. 80 and 144; 1967 Nos. 67, 116 and 158; 1968 No. 44
	am. 1968 No. 88
	rs. 1968 No. 146
	am. 1969 No. 44
	rs. 1969 No. 107
	am. 1969 No. 185
	rs. 1970 Nos. 39 and 94
	am. 1970 Nos. 119 and 186
	rs. 1971 Nos. 44, 101 and 154; 1972 No. 32
	am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57
	rs. 1973 No. 139
	am. 1973 No. 229; 1974 No. 37
	rs. 1974 No. 126
	am. 1974 No. 222; 1975 No. 50
	rs. 1975 No. 148
	am. 1975 No. 209
	rs. 1976 No. 84
	am. 1976 Nos. 150 and 255; 1977 No. 39

## Endnote 4—Amendment history

<b>Provision affected</b>	<b>How affected</b>
Schedule 5 .....	am. 1977 No. 39 rs. 1977 No. 125 am. 1977 No. 221; 1978 Nos. 47 and 142 rs. 1978 No. 245 am. 1979 No. 51 rs. 1979 No. 144 am. 1979 No. 250; 1980 Nos. 69 and 213 rs. 1980 No. 338 am. 1981 No. 52 rs. 1981 No. 212 am. 1981 No. 345; 1982 No. 76 rs. 1982 No. 179 am. 1982 No. 334; 1983 No. 28 rs. 1983 No. 116 am. 1983 No. 292; 1984 Nos. 50, 169 and 342 rs. 1985 Nos. 32 and 184 am. 1985 No. 320; 1986 No. 38 rs. 1986 No. 194 am. 1986 No. 320 rep. 1987 No. 47
Heading to Sixth Schedule.....	rep. 1977 No. 39
Heading to Schedule 6 .....	ad. 1977 No. 39 rep. 1994 No. 348
Schedule 6 .....	am. 1977 No. 39 rs. 1981 No. 218 am. 1984 No. 148 rep. 1994 No. 348
Heading to Schedule 7 .....	rs. 1991 No. 1 rep. 1994 No. 348
Schedule 7 .....	ad. 1983 No. 102 rep. 1986 No. 319

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
	ad. 1987 No. 262
	rep. 1994 No. 348

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